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Providers Will Be Asked to Register to Receive Medicare Bulletins and Newsletters
During this fiscal year, Medicare Contractors will be required to register providers/suppliers to receive hard copy bulletins and newsletters. First Coast Service Options, Inc. is developing a process in accordance with the guidelines issued by the Health Care Financing Administration.
At this time there is no need to contact your Medicare Contractor, you will be notified regarding this new registration requirement in the near future, via your Medicare B Update!

The Medicare B Update! should be shared with all health care practitioners and managerial members of the provider/supplier staff. Issues published beginning in 1997 are available at no cost from our provider Website, www.FloridaMedicare.com.

- Physician/Provider
- Office Manager
- Billing/Vendor
- Nursing Staff
- Other

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The Medicare B Update! is published by the Medicare Publications Department of First Coast Service Options, Inc., to provide timely and useful information to Medicare Part B providers in Florida.

Questions concerning this publication or its contents may be directed in writing to:

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“Why Should I Comply?”

As I attend meetings with my colleagues, I frequently hear comments about the OIG Compliance Plan. Comments range from “How can I get mine implemented now?” to “They can’t make us do this!”

First of all, there is now a model plan published on the Office of Inspector General (OIG) web site, http://www.hhs.gov/progorg/oig/modcomp/index.htm, dated 10/06/2000. The title is “The Office of Inspector General Compliance Program Guidance for Individual and Small Group Physician Practices.” Second, the program is entirely voluntary and is provided only to help small practices design effective compliance programs. The OIG’s goal is to show that compliance can become part of the practice culture without spending a lot of money or time. I have never known a physician who admitted to knowingly submitting a claim in error. I know a lot who have submitted erroneous claims due to lack of correct information or lack of due diligence.

No prudent person would operate a business without effective internal financial controls. For instance, if you allow the person who makes the office deposits to also write the office checks, it would be easy for that person to misappropriate your funds. Incorrect billing over a period of time can set you up for a substantial overpayment/repayment situation. Your compliance program should minimize this risk to your practice. The OIG has tried to simplify the process by providing you a template to follow in setting up your program.

A word of caution: a compliance program in a book on your bookshelf is of little value to anyone unless the process is actually put into action. Consider carefully how you wish to monitor your practice, document the process clearly in your compliance manual, and insist upon all staff members following the plan.

The OIG’s recommended plan is based upon seven standard components and emphasizes a step-by-step approach for practices to follow. As a first step, you should identify risk areas that might benefit from closer scrutiny and corrective/educational measures. The Florida Medicare Contractor, First Coast Service Options, Inc. (FCSO) recovered or prevented $448,600,000 in overpayments last year, so there must be a lot of incorrect billing.

The seven components of the recommended OIG Compliance Plan are:

1. Conducting internal monitoring and auditing through the performance of periodic audits.
2. Implementing compliance and practice standards through the development of written standards and procedures.
3. Designating a compliance officer or agent to monitor compliance efforts and enforce practice standards.
4. Conducting appropriate training and education on practice standards and procedures.
5. Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate Government entities.
6. Developing open lines of communication to keep practice employees updated regarding compliance activities.
7. Enforcing disciplinary standards through well-publicized guidelines.

The final guidance also identifies four specific compliance risk areas for practicing physicians:

1. Proper coding and billing.
2. Ensuring that services are reasonable and necessary.
3. Proper documentation.
4. Avoiding improper inducements, kickbacks and self-referrals.

“Why should I comply?” Quite simply, because it is the right thing to do. It will enhance correct billing, reduce rework, increase billing efficiency, and minimize the risk of a substantial overpayment. In short, “The gain will far outweigh the pain.”

Sincerely,

Sidney R. Sewell, M.D.
Medical Director
General Information About the Medicare B Update!

Articles included in each Update! represent formal notice that specific coverage policies either have or will take effect on the date given. Providers who receive each issue are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines. Florida Medicare Part B maintains copies of the mailing lists for each issue, and inclusion on these mailing lists implies that the issue was received by the provider in the event there is a dispute over whether a provider received advance notice regarding coverage of a specific service and the financial liability for it.

Distribution of the Update! is limited to individual providers and professional association (PA) groups who bill at least one claim to Florida Medicare Part B for processing during the twelve months prior to the release of each issue. Providers meeting this criteria are sent one complimentary copy of that issue. Production, distribution, and postage costs prohibit distributing a copy to all of a provider’s practice settings. This primarily affects members of PA groups; one copy of each issue is sent to the group. The group is responsible for dissemination of each copy to its members. For additional copies, providers may purchase a separate annual subscription for $75 (see order form on page 107).

Florida Medicare Part B uses the same mailing address for all correspondence, and cannot designate that each issue of the Update! be sent to a specific person/department within a provider’s office. To ensure continued receipt of all Medicare correspondence, providers must keep their mailing addresses current with the Medicare Registration Department.

About the Format
The Update! is divided into several sections, starting with an article by the Carrier Medical Director. Following is Administrative information, then Claims, that provides claims submission requirements and tips. Correspondence (appeals and hearings) information is in this section. Coverage/Reimbursement discusses CPT and HCPCS procedure codes. It is arranged by specialty categories (not specialties). For example, “Mental Health” presents coverage information of interest to psychiatrists, clinical psychologists and clinical social workers. Also presented in this section are changes to the Medicare Physician Fee Schedule (MPFS) and other pricing issues. Local and Focused Medical Review Policies follows, then General Information (other information for Medicare providers including Fraud and Abuse issues), and Educational Resources that includes seminar schedules and reproducible forms, and important addresses, phone numbers and websites for seminar registration (appeals and hearings) information is in this section. Coverage/Reimbursement discusses CPT and HCPCS procedure codes. It is arranged by specialty categories (not specialties). For example, “Mental Health” presents coverage information of interest to psychiatrists, clinical psychologists and clinical social workers. Also presented in this section are changes to the Medicare Physician Fee Schedule (MPFS) and other pricing issues. Local and Focused Medical Review Policies follows, then General Information (other information for Medicare providers including Fraud and Abuse issues), and Educational Resources that includes seminar schedules and reproducible forms, and important addresses, phone numbers and websites for seminar registration.

Advance Notice Requirement
The following information applies to all articles in this publication referencing services that must meet medical necessity requirements (e.g., services with specific diagnosis requirements). Refer to this information for articles that indicate advance notice applies.

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for the treatment/diagnosis of the patient. For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (utilization screen - i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare’s possible denial of payment if the provider does not want to accept financial responsibility for the service or item. The advance notice must meet the following requirements:

- The notice must be given in writing, in advance of furnishing the service or item.
- The notice must include the patient’s name, date(s) and description of the service or item, and the reason(s) why the service or item may not be considered medically reasonable and necessary (e.g., the service is not covered based on the diagnosis of the patient, the frequency of the service was furnished in excess of the utilization screen, etc.).
- The notice must be signed and dated by the patient indicating that the patient assumes financial responsibility for the service if payment is denied as being not medically reasonable and necessary for the reason(s) indicated on the advance notice. The signature of the provider of service is not required.

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting procedure code modifier GA with the service or item. The advance notice form should be maintained with the patient’s medical record.

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.
Proper Reporting of Diagnoses on a Claim

Florida Medicare’s Medical Policy department frequently receives requests from providers to change our coverage policies because “their claims are not getting paid.” Analysis of these claims revealed that the problem is often not with the local medical review policies, but with incorrect billing procedures. Failure to list the correct diagnoses is one of the most frequent reasons for claim rejections. The patient’s diagnosis code must be reported to the highest level of specificity as listed in the latest edition of the ICD-9-CM.

Physicians frequently enter in their patients’ records a complete list of past diagnoses (e.g., post-cholecystectomy, post-MI) as a reminder and as a matter of thoroughness. Chronic diseases treated on an ongoing basis should be coded and reported on claims as many times as the patient receives treatment and care for those conditions. However, conditions that no longer require treatment should not be submitted on subsequent claims.

It is important to realize that one cannot use the results of a test to justify performance of a test. For example, if during an annual exam a patient who has not been previously diagnosed as diabetic records an elevated blood sugar, the claim should not be submitted with the diagnosis of diabetes; but as a screening blood glucose.

If the diagnosis is unknown, the physician should report the signs and symptoms related to the visit. For example, if a physician sees a patient who has symptoms of “dizziness and double vision” and starts a work-up to “rule out multiple sclerosis,” the reason given for the visit should be “dizziness and double vision” and not “multiple sclerosis.” The same rationale holds true when referring patients for lab tests or X-rays. For example, if a physician sees a patient with “dizziness, headache and nausea” and orders a CT scan to “rule out brain tumor,” the physician should report “dizziness, headache and nausea” on the request and not “brain tumor.” This is true even if the CT shows a tumor.

Providers are strongly encouraged to purchase the 2001 ICD-9-CM manual to assist in determining the appropriate diagnosis to bill with specific procedures. Providers may also obtain a copy of Florida Medicare’s “Procedure to Diagnosis Report,” by using the order form on page 107 of this publication.

The Use of Modifiers 59 and 25 with Evaluation and Management (E/M) Codes

In 1996, the Health Care Financing Administration (HCFA) established modifier GB (distinct procedural service). As a result of the 1997 HCPCS update, however, modifier GB was deleted and replaced with modifier 59.

Modifier 59 represents a procedure that is a ‘distinct procedure or service from others billed on the same date of service.’ It may represent a different session, different surgery, different anatomical site, different agent, different lesion, different injury or area of injury. Modifier 59 should be used only in those instances where another modifier does not exist to indicate a separate procedure.

Based on section 4630 of the Medicare Carriers Manual (MCM), modifier 59 should not be used with the following procedure codes:

77419-77430 (Weekly radiation therapy management codes)
99201-99499 (Evaluation and management services)

Modifier 25 (separate E/M service), not 59, should therefore be used to identify situations when an E/M service is separately identifiable from another service. When E/M claims are received with modifier 59, the modifier is dropped, which may cause the E/M service to be denied. Providers should indicate modifier 25 on the E/M service if a separate identifiable service was rendered.

Influenza, Pneumococcal, and Hepatitis B Vaccine Administrations Billed in Conjunction with Evaluation and Management Services

Previously, if one of the three HCPCS codes listed below was billed with an evaluation and management (E/M) code on the same day of service, Medicare carriers required modifier 25 to be appended to the E/M code for payment. This requirement has been rescinded, effective for services processed on and after December 22, 2000.

Providers should resubmit claims with E/M codes and the HCPCS listed below that have been denied. Although the use of a modifier is not required at this time; as a reminder, an E/M code should not be billed for a vaccination procedure unless a separately identifiable service was performed.

G0008 Administration of influenza virus vaccine
G0009 Administration of pneumococcal vaccine
G0010 Administration of hepatitis B vaccine
Health Professional Shortage Area (HPSA) Designation Changes

A complete list of HPSA designations was published in the January/February 2000 Medicare B Update! (page 7-9). Updates to the HPSA list were subsequently published in the May/June 2000 (page 7) and July/August 2000 (page 5) issues.

Effective for claims processed on or after December 1, 2000, the following changes have been made for Dade County - all of Model Cities census tract were removed:

- 0004.08
- 0008.01
- 0008.02
- 0009.01
- 0009.02
- 0009.03
- 0010.01
- 0010.02
- 0010.03
- 0010.04
- 0011.03
- 0015.01
- 0015.02
- 0016.01
- 0016.02
- 0017.01
- 0017.02
- 0018.01
- 0018.02
- 0018.03
- 0019.01
- 0019.03
- 0019.04
- 0023.00

In addition, effective for claims processed on or after March 1, 2001, the following changes have been made for Nassau County - census tracts 504 and 505 (Callahan/Hilliard) were removed:

For more information regarding HPSAs, please refer to the aforementioned article in the January/February 2000 Update!

Ambulance Fee Schedule

The following article was previously provided to all ambulance suppliers in Florida.

At press time, HCFA has announced a delay in the implementation of certain components of the Ambulance Fee Schedule. Important information regarding this delay may be found on pages 9-10.

The Health Care Financing Administration (HCFA) plans to implement a new payment system for medically necessary transports effective for services provided on or after January 1, 2001 based on section 4531 (b) (2) of the Balanced Budget Act of 1997 (which added a new section [1834 (l)] to the Social Security Act). This new payment system will involve new HCPCS codes, payment methods, and claim requirements. HCFA will no longer pay for these services based on reasonable charges or reasonable cost. Instead, payment will be made from a fee schedule. The fee schedule applies to all ambulance services, including volunteer, municipal, private, independent, and institutional providers (i.e., hospitals, critical access hospitals, skilled nursing facilities and home health agencies).

This publication provides a basic overview of the new Ambulance Fee Schedule payment system, including the transition schedule and delayed implementation of certain components. Please refer to HCFA Program Memoranda (PM) AB-00-88 and AB-00-118, issued on September 18, 2000 and November 30, 2000 respectively, for more information. Copies of these PMs may be downloaded at www.hcfa.gov/medlearn/refamb.htm.

Ambulance services will be reported on claims using new HCPCS codes that reflect the seven categories of ground service and two categories of air service.

Mandatory assignment is required for all ambulance services when the fee schedule is implemented.

The fee schedule will be phased in over a four-year period. When fully implemented, the fee schedule will replace the current retrospective reasonable cost reimbursement system for providers and the reasonable charge system for ambulance suppliers.

Categories of Ambulance Services

There are seven categories of ground ambulance services and two categories of air ambulance services under the new fee schedule. The ground service categories refer to both land and water transportation and are listed below:

The ground service categories include:
1. Basic Life Support
2. Basic Life Support – Emergency
3. Advanced Life Support, Level 1
4. Advanced Life Support, Level 1 – Emergency
5. Advanced Life Support, Level 2
6. Specialty Care Transport
7. Paramedic Intercept
The air service categories include:
1. Fixed Wing Air Ambulance (airplane)
2. Rotary Wing Air Ambulance (helicopter)
3. Paramedic Intercept (PI)
4. Specialty Care Transport (SCT)

The HCPCS codes used to report these services may be found on page 7.

Ground Services
Ground services are reimbursable if they meet Medicare medically necessary coverage guidelines. An emergency response is one that, at the time the ambulance is called, is provided after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the beneficiary’s health in serious jeopardy; in impairment to bodily functions; or in serious dysfunction to any bodily organ or part.

Ground Services Category Definitions

Basic Life Support (BLS) — The provision of basic life support services as defined by the National EMS Education and Practice Blueprint from EMT, including the establishment of a peripheral intravenous (IV) line.

Basic Life Support (BLS) – Emergency —
The provision of BLS services as described above, in the context of an emergency response.

Advanced Life Support, Level 1 (ALS1) —
The provision of an assessment by an advanced life support (ALS) provider or supplier or the provision of one or more ALS interventions. An ALS provider/supplier is defined as a provider trained to the level of the EMT-Intermediate or Paramedic as defined in the National EMS Education and Practice Blueprint. An ALS intervention is defined as procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint.

Advanced Life Support, Level 1 (ALS1 – Emergency) —
The provision of ALS1 services, as specified above, in the context of an emergency response.

Advanced Life Support, Level 2 (ALS2) —
The administration of three or more different medications and the provision of at least one of the following ALS procedures:
- Manual defibrillation/cardioversion
- Endotracheal intubation
- Central venous line
- Cardiac pacing
- Chest decompression
- Surgical airway
- Intraosseous line

Advanced life support (ALS) assessment is an assessment performed by an ALS crew that results in the determination that the patient’s condition requires an ALS level of care, even if no other ALS intervention is performed.

NOTE: As a clarification, the following is the definition of “emergency” for the BLS and ALS1 levels of service:
An ambulance service that qualifies as an emergency response will be assigned a higher relative value to recognize the additional costs incurred in responding immediately to an emergency medical condition. An immediate response is one in which the ambulance provider begins as quickly as possible to take the steps necessary to respond to the call. There is no emergency modifier for PI, ALS2, or SCT.

Specialty Care Transport (SCT) — A level of inter-facility service, for a critically injured or ill beneficiary, provided beyond the scope of the paramedic as defined in the National EMS Education and Practice Blueprint. This is necessary when a beneficiary’s condition requires ongoing care that must be provided by one or more health professionals in an appropriate specialty area, e.g., nursing, medicine respiratory care, cardiovascular care, or a paramedic with additional training. Florida Medicare processes all claims for SCT on an individual consideration (IC) basis.

Paramedic Intercept (PI) — Paramedic intercept services are ALS services provided by an entity that does not provide the ambulance transport. Under a limited number of circumstances, Medicare payment may be made for these services. NOTE: the Paramedic Intercept provision is not applicable in most geographical areas, including all of Florida.

Air Services
Air services are reimbursable when transport meets Medicare coverage requirements, and the beneficiary’s medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Florida Medicare processes all claims for air services on an IC basis.

Higher operational costs for the two types of aircraft are recognized with two distinct payment amounts for air ambulance mileage. The air ambulance mileage rate is calculated per actual loaded (patient onboard) miles flown and is expressed in statute miles (not nautical miles).

Air Services Category Definitions

Fixed Wing Air Ambulance (FW) — Transport by fixed wing air ambulance may be necessary because the beneficiary’s condition requires rapid transport to a treatment facility, and either great distances or other obstacles (e.g., heavy traffic) preclude such rapid delivery to the nearest appropriate facility. Transport by fixed wing air ambulance may also be necessary because the beneficiary is inaccessible by a land or water ambulance vehicle.

Rotary Wing Air Ambulance (RW) — Transport by rotary wing air ambulance may be necessary because the beneficiary’s condition requires rapid transport to a treatment facility, and either great distances or other obstacles (e.g., heavy traffic) preclude such rapid delivery to the nearest appropriate facility. Transport by rotary wing air ambulance may also be necessary because the beneficiary is inaccessible by a land or water ambulance vehicle.

New HCPCS Codes for Ambulance Services
As a result of the implementation of the national ambulance fee scheduled initiative, claims for ambulance services furnished on or after January 1, 2001, must be reported using the new HCFA common procedure coding system (HCPCS) codes:
A0425* BLS mileage (per mile) * A0425 should not be used at this time. Providers should continue to bill for mileage using code A0380 or A0390, as appropriate. See page 10 for more information regarding the delay in implementation of code A0425.

A0426 Ambulance service, ALS, non-emergency transport, specialized ALS services rendered, supplies included, mileage separately billed

A0427 Ambulance service, ALS, emergency transport, specialized ALS services rendered, supplies included, mileage separately billed

A0428 Ambulance service, BLS, non-emergency transport, supplies included, mileage separately billed

A0429 Ambulance service, basic life support (BLS), emergency transport, water, special transportation services

A0429 Ambulance service, BLS, emergency transport, supplies included, mileage separately billed

A0430 Ambulance service, conventional air services, transport, one way, fixed wing (FW)

A0431 Ambulance service, conventional air services, transport, one way, rotary wing (RW)

A0432 Paramedic ALS Intercept (PI), rural area transport furnished by a volunteer ambulance company which is prohibited by state law from billing third party payers.

A0433 Ambulance service, ALS2, supplies included, mileage separately billed

A0434 Ambulance service, SCT, supplies included, mileage separately billed

A0435 Air mileage; FW, (per statute mile)

A0436 Air mileage; RW, (per statute mile)

A0999 Unlisted ambulance service

HCFA has developed a crosswalk of the new HCPCS codes to the old codes. This list, including descriptors, is Attachment B of HCFA PM AB-00-88. The crosswalk is also available on our provider Website - www.floridamedicare.com - in the Ambulance Fee Schedule Special Issue Medicare B Update! dated December 18, 2000

Changes Associated with the Ambulance Fee Schedule Initiative

When the ambulance fee schedule initiative is implemented, payment for ambulance services will be based on items and services provided, not on the vehicle used. Even if a local government requires an ALS response for all calls, Medicare pays only for the level of services provided and then only when the services are both medically necessary and covered by Medicare under the ambulance benefits.

Payment under the fee schedule for ambulance services is comprised of a base rate payment plus a separate payment for mileage. This base rate includes both the transport of the beneficiary to the nearest appropriate facility and all items and services associated with the transport. The base rate precludes a separate payment for items and services. Such items and services include, but are not limited to items that are both medically necessary and Medicare-covered such as oxygen, drugs, extra attendants, and EKG testing.

When the ambulance fee schedule is implemented, services will be paid based on the lower of the actual billed amount or the ambulance fee schedule amount (see page 10 for more information about the implementation date). The fee schedule will be phased in over a four-year period and when fully implemented will replace the current retrospective reasonable cost reimbursement system for providers and reasonable charge system for ambulance suppliers. Contractor reimbursement rates will be based on the supplier’s current billing methodology during the transition period.

Claims jurisdiction remains unchanged for the duration of the transition to the fee schedule.

Ambulance Fee Schedule Components

Ground Ambulance Services

1. Conversion Factor (CF) — Money amount that serves as a nationally uniform base rate for all ground ambulance services and will be updated as necessary.

2. Relative Value Unit (RVU) — A numeric value assigned to each category of ground ambulance service relative to the value of a base level of ambulance service (the BLS level).

<table>
<thead>
<tr>
<th>Service Level</th>
<th>RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>BLS</td>
<td>1.00</td>
</tr>
<tr>
<td>BLS – Emergency</td>
<td>1.60</td>
</tr>
<tr>
<td>ALS1</td>
<td>1.20</td>
</tr>
<tr>
<td>ALS1 – Emergency</td>
<td>1.90</td>
</tr>
<tr>
<td>ALS2</td>
<td>2.75</td>
</tr>
<tr>
<td>SCT</td>
<td>3.25</td>
</tr>
<tr>
<td>PI</td>
<td>1.75</td>
</tr>
</tbody>
</table>

3. Geographic Adjustment Factor (GAF) — The non-facility practice expense (PE) of the geographic practice cost index (GPCI) of the Medicare physician fee schedule used to address regional differences in the cost of furnishing ambulance services for each ambulance fee schedule area. The location used is the one at which the beneficiary put in the ambulance.

4. Mileage — A nationally uniform loaded mileage rate of $5 per loaded statute mile except for the paramedic intercept (PI) category. Mileage is not billable for PI services.

5. Rural Area Mileage Adjustment — For services furnished in a rural area, an additional amount for mileage to account for higher costs typical to rural operations. The increase to the mileage rate is 50 percent (up to $7.50) per loaded statute mile for the first 17 miles. HCFA will provide files to contractors that identify rural/urban ZIP codes.

Air Ambulance Services

1. Base Rate — The national uniform base rate for fixed wing is $2213.00. The national uniform base rate for rotary wing is $2573.00. No conversion factor or RVU is applied.

2. Geographic Adjustment Factor (GAF) — Applied in the same manner as the ground ambulance services, except the applicable GPCI is applied to 50 percent of each of the base rates (fixed and rotary wing).

3. Mileage — A nationally uniform loaded mileage rate of $6 per loaded statute mile flown for fixed wing services and $16 per loaded statute mile flown for rotary wing services.
4. Rural Area Mileage Adjustment — For services furnished in a rural area, an additional 50 percent of the unadjusted fee schedule amount to account for higher costs typical to rural operations.

Point of Pickup

Point of pickup, as identified by the five-digit ZIP code, establishes if a rural adjustment applies. Each leg of multi-leg transports is separately evaluated for rural adjustment application determined by the point of pickup for each leg.

Rural Area, with the exception of the paramedic intercept category, is defined as a U.S. Postal Service ZIP Code that is located in whole or in part, outside of either a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), or is an area wholly within a MSA or NECMA that has been identified as rural under the “Goldsmith modification.” (The Goldsmith modification establishes an operational definition of rural areas within large counties that contain one or more metropolitan areas. The Goldsmith areas are so isolated by distance or physical features that they are more rural than urban in character and lack easy geographic access to health services.)

Transition Schedule

When the ambulance fee schedule is implemented, payment under the schedule will be phased-in over a four-year period.

Initially, the fee schedule amount will comprise only 20 percent of the amount allowed from Medicare and the remaining 80 percent allowed by Medicare for a service furnished in year 1 of the transition will be based on the supplier’s reasonable charge. Thereafter, the fee schedule amount will increase each calendar year as a percentage of the allowed amount until it reaches 100 percent in year 4. Thus, in year 1, year 2, and year 3, the amount allowed for an ambulance service will be the lower of the submitted charge or a blended rate that comprises both a fee schedule component and a provider’s reasonable cost or a supplier’s reasonable charge.

The phase-in schedule is as follows:

<table>
<thead>
<tr>
<th>Fee Schedule Year</th>
<th>Fee Schedule Percentage</th>
<th>Reas. Charge Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>20%</td>
<td>80%</td>
</tr>
<tr>
<td>Year 2</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Year 3</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Year 4</td>
<td>100%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Calculating the Blended Rate during the Transition

Suppliers are currently paid based on a reasonable charge methodology. For services furnished during the transition period, payment of ambulance services will be a blended rate that consists of both a fee schedule component and a provider or supplier’s current payment methodology as follows:

The blended rate includes both a portion of the reasonable charge and the fee schedule amount. For the purpose of implementing the transition to the fee schedule, the reasonable charge for each supplier is adjusted for each year of the transition period by the ambulance inflation factor as published by HCFA.

A supplier specific charge will be established for the new HCPCS mileage code A0425 using a simple average (not weighted) from the supplier’s specific reasonable charge for the old mileage codes A0380 and A0390. This average will be used as the reasonable charge for 2001 and updated by the Ambulance Inflation Factor.

New HCPCS Codes

- HCPCS codes A0426 through A0436 must be used effective with service dates on or after January 1, 2001. However, these codes are not valid for service dates prior to January 1, 2001.
- No grace period will be provided to transition the use of the new HCPCS codes (except A0380 and A0390 – see page 10 for more information).
- Claims submitted with old HCPCS codes for dates of service on or after January 1, 2001 will be returned as unprocessable.

Factors Impacting Payment

Categories of Service

Medicare pays only for the category of service provided and then only when it is medically necessary.

Multiple Patients

More than one patient may be transported; e.g., from the scene of a traffic accident. The fee should be prorated by the number of patients in the ambulance. Medicare Part B coinsurance, deductible, and mandatory assignation apply to this prorated amount.

Pronouncement of Death

The following two scenarios apply to payment for ambulance services when the beneficiary dies. No payment will be made if the beneficiary was pronounced dead prior to the time the ambulance is called.

1. The beneficiary is pronounced dead after the ambulance is called but before the ambulance arrives at the scene: Payment may be made for a BLS service if a ground vehicle is dispatched or at the fixed wing or rotary wingbase rate, as applicable, if an air ambulance is dispatched. (For suppliers, there will be only one line item for this situation.) Neither mileage nor a rural adjustment would be paid. The blended rate amount will otherwise apply. Suppliers continue to use the QL modifier.

2. The beneficiary is pronounced dead after being loaded into the ambulance (regardless of whether pronounced during or subsequent to the transport): Payment is made following the usual rules of payment as if the beneficiary had not died. This scenario includes a determination of “dead on arrival” (DOA) at the facility to which the beneficiary was transported.

NOTE: Notwithstanding the beneficiary’s apparent condition, the death of a beneficiary should be recognized only when the pronouncement of death is made by an individual who is licensed or otherwise authorized under State law to pronounce death in the State where such pronouncement is made.

Multiple Arrivals

When multiple units respond to a call for services, the entity that provides the transport for the beneficiary bills for all services furnished. If BLS and ALS entities respond to a call and the BLS entity furnishes the transport after an ALS assessment was furnished, the BLS entity will bill using the ALS1 rate. The BLS entity will be paid at the ALS1 rate. The BLS entity and the ALS entity settle payment for the ALS assessment.
HCPCS Codes for Service and Mileage

Individual HCPCS codes for service and mileage along with specific ZIP codes and number of miles must be reflected on the claim so accurate claim processing can occur.

Since the ZIP code is used for pricing, more than one ambulance service may be reported on the same claim for a beneficiary if all points of pickup have the same ZIP code. Prepare a separate claim for each trip if the points of pickup are located in different ZIP codes.

Concepts Impacting Coding

The implementation of the Ambulance Fee Schedule has generated some new coding requirements. The following are the concepts that will now drive the ambulance coding requirements:

- Seven categories of ground ambulance services
- Two categories of air ambulance services
- Payment based on the condition of the beneficiary, not on the type of vehicle used
- Payment is determined by the point of pickup as reported by the five-digit ZIP code
- Increased payment for rural services
- New HCPCS codes effective for dates of service beginning January 1, 2001
- Services and supplies included in base rate
- No grace period for old HCPCS for dates of service after January 1, 2001 (except codes A0380 and A0390; see page 10 for more information)

HCFA-1500 Claim Form Coding Instructions

Medicare pays only for the category of service provided and then only when the service is medically necessary.

Generally, each ambulance trip will require two lines of coding; i.e., one line for the service and one line for the mileage. Suppliers who do not bill mileage would have one line of code for the service.

If mileage is billed, report the miles as whole numbers. If a trip has a fraction of a mile, round up to the nearest whole number. Code “1” as the mileage for trips of less than a mile.

More than one ambulance service may be reported on the same claim for a beneficiary if all points of pickup have the same ZIP code. Suppliers must prepare a separate claim for each trip if the points of pickup are located in different ZIP codes.

Generally, a claim for an ambulance service will require two entries; one HCPCS code for the service and one HCPCS code for the mileage. Suppliers who do not bill mileage would have an entry only for the service.

In item 22, enter the service HCPCS code, as well as any information necessary to describe the illness or injury.

In item 14, the mileage HCPCS code, as well as the number of loaded miles.

Implementation Date of the Ambulance Fee Schedule

On November 30, 2000, HCFA announced a delay in the implementation of the ambulance fee schedule. This means that payment for ambulance services will be made based on 100 percent of the allowance under the current payment rules (updated for inflation as described in PM AB-00-88) and not on the basis of the “80 percent current/20 percent fee schedule” blend methodology.

Although implementation of the fee schedule is delayed, implementation of the new HCPCS codes for ambulance services and requirement to report the ZIP code of the point of pickup on the claim is not delayed. Therefore, the new HCPCS codes and reporting the ZIP code of the point of pickup are effective with services furnished on or after January 1, 2001.

Delay Mandatory Assignment for Ambulance Services

Based on PM AB-00-88, “Implementation of the Ambulance Fee Schedule,” released September 18, 2000, contractors were to make systems changes to assure that claims for ambulance services follow mandatory assignment rules. Contractors have been instructed not to revise their systems with regard to mandatory assignment until further notice. However, when mandatory assignment becomes effective, it may be necessary for contractors to enforce mandatory assignment for ambulance services through administrative actions.

ALS Vehicle used, but No ALS Service Furnished

Also based on PM AB-00-88, suppliers and providers using an ALS vehicle to furnish a BLS level of service are instructed to report on the claim HCPCS A0428 or A0429, the new HCPCS code for BLS and BLS emergency, respectively. This policy is not being implemented at this time. Until further notice, these claims must be submitted with the new HCPCS code, A0426 (ALS1) or A0427 (ALS1 emergency); contractors will process accordingly.
Payment for Mileage

Until further notice, suppliers should submit claims with the appropriate current codes, A0380 for BLS mileage and A0390 for ALS mileage. Contractors will not accept for processing any claim with the new code, A0425, until further notice.

The reasonable charge for services furnished in calendar year 2001 for A0380 and A0390 will be calculated on a supplier specific basis by multiplying each supplier’s reasonable charge for 2000 by the ambulance inflation factor.

Payment Based upon the Condition of the Beneficiary

The regulation for ambulance fee schedule also includes a clarification of the policy for payment. Payment will be based on the condition of the beneficiary and the services rendered by the crew. The vehicle dispatched does not determine payment. This policy is also delayed until a final regulation implementing the fee schedule becomes effective.

Components of Ambulance Fee Schedule that are Effective

January 1, 2001

Even though there is a delay in the implementation date of the fee schedule, most requirements from Program Memorandum AB-00-88 remain effective for January 1, 2001 except: payment using the fee schedule, ALS vehicle used but no ALS service rendered, mandatory assignment for carriers, and payments based on the condition of the beneficiary. These items are explained above.

The requirements that remain effective January 1, 2001 include:

• New HCPCS codes
• No grace period for old ambulance codes (except A0380 and A0390) - There will be no grace period for most ambulance codes. The only codes with a grace period are the mileage codes A0380 and A0390, which will be used until the fee schedule is implemented.

• ZIP code on the claim - Carriers will continue to pay ambulance claims on a reasonable charge basis until the fee schedule is implemented by a final rule. Although payment amount is not based on the ZIP code (since this is a facet of fee schedule), the ZIP code is required as part of the claim information. Submitted ZIP codes that are invalid will result in the claim being returned as unprocessable. Suppliers should use “00000” as the ZIP code for foreign claims.

• ALS transportation but no ALS service allowed at ALS1 - Until the fee schedule is implemented, there is a coding exception for ALS transport provided but no ALS service rendered; i.e., codes A0324, A0328, A0344 and A0348. When this occurs, the supplier should code ALS1 or ALS1 emergency. Once the fee schedule is implemented, ambulance services must reflect the service provided based on the condition of the beneficiary.

Further information regarding implementation of the Ambulance Fee Schedule will be provided on our provider Website – www.floridamedicare.com – and in future issues of the Medicare B Update! as it becomes available from HCFA. Suppliers may also call our Provider Customer Service department toll-free at 1-877-847-4992.

This publication was produced prior to the publication of the final rule implementing Medicare’s Ambulance Fee Schedule Payment System. We have incorporated the best information available at the time of publication. Please refer to the final rule when published in the Federal Register for authoritative guidance on this new system. This publication should not be considered an authoritative source in making Medicare program policy determinations.

2001 Prevailing Allowances for Ambulance Services

Prevailing fee allowances for the new and updated ambulance HCPCS codes described on page 7 are listed below. Customary fee allowances were previously provided to ambulance suppliers, and may differ from the amounts shown here. These fees are effective beginning January 1, 2001 and will remain in effect until the Ambulance Fee Schedule is implemented.

<table>
<thead>
<tr>
<th>CODE</th>
<th>LOC 01</th>
<th>LOC 02</th>
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<tr>
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<td>134.79</td>
<td>179.32</td>
<td>186.44</td>
<td>166.45</td>
</tr>
<tr>
<td>A0426</td>
<td>271.86</td>
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<td>313.80</td>
<td>303.79</td>
</tr>
<tr>
<td>A0427</td>
<td>271.86</td>
<td>312.73</td>
<td>313.80</td>
<td>303.79</td>
</tr>
<tr>
<td>A0380</td>
<td>4.31</td>
<td>4.94</td>
<td>6.41</td>
<td>7.19</td>
</tr>
<tr>
<td>A0390</td>
<td>4.31</td>
<td>4.94</td>
<td>6.41</td>
<td>7.19</td>
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<tr>
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<td>16.81</td>
<td>16.81</td>
</tr>
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<td>A0435</td>
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<td>IC</td>
<td>IC</td>
<td>IC</td>
</tr>
<tr>
<td>A0436</td>
<td>IC</td>
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<td>IC</td>
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<tr>
<td>A0380</td>
<td>4.31</td>
<td>4.94</td>
<td>6.41</td>
<td>7.19</td>
</tr>
<tr>
<td>A0390</td>
<td>4.31</td>
<td>4.94</td>
<td>6.41</td>
<td>7.19</td>
</tr>
</tbody>
</table>
AMBULATORY SURGERY CENTER

The List of Procedures Approved in an Ambulatory Surgical Center

The following is a current inclusive list of surgical procedures that may be reimbursed when billed by an Ambulatory Surgical Center (ASC). The first number in each column is the procedure code; the second is its ASC payment group. Facility charges for procedures other than those on the list are not covered by Medicare, although the physician’s fee may be payable. The beneficiary is liable for such noncovered facility charges; waiver of liability does not apply.

As a result of the American Medical Association’s (AMA) January 1, 2001, update for the Current Physician’s Terminology (CPT) book, some codes on the previous list have been deleted. Replacement codes, where applicable, are added to the list for services furnished on or after January 1, 2001. This information was published in the December 2000 Special Issue Medicare B Update! (page 1); however, an error has been identified in that article. The replacement code for the deleted CPT code 52335 is 52351, not 52338. Florida Medicare apologizes for any inconvenience this error may have caused.

Additionally, CPT code 62263 was previously noncovered. Effective for services rendered on or after January 1, 2000, processed on or after March 19, 2001, 62263 is a covered procedure. The facility charge for 62263 is payable under ASC payment group 1.
Second Quarter 2001 The Florida Medicare B Update!
Second Quarter 2001 The Florida Medicare B Update!
**ANESTHESIA**

**Revised 2001 Anesthesia Conversion Factors**

The 2001 national anesthesia conversion factors that were sent out in the annual fee disclosure package have been corrected by the Health Care Financing Administration (HCFA).

The 2001 national anesthesia conversion factor is $17.83, not $17.26. The revised locality-specific anesthesia conversion factors for Florida are:

<table>
<thead>
<tr>
<th>Participating</th>
<th>Loc 01/02</th>
<th>Loc 03</th>
<th>Loc 04</th>
<th>Nonparticipating</th>
<th>Loc 01/02</th>
<th>Loc 03</th>
<th>Loc 04</th>
<th>Limiting Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loc 01/02</td>
<td>17.72</td>
<td>18.90</td>
<td>20.06</td>
<td>Loc 01/02</td>
<td>16.83</td>
<td>17.96</td>
<td>19.06</td>
<td>Loc 01/02</td>
</tr>
<tr>
<td>Loc 03</td>
<td></td>
<td></td>
<td></td>
<td>Loc 03</td>
<td></td>
<td></td>
<td></td>
<td>Loc 03</td>
</tr>
<tr>
<td>Loc 04</td>
<td></td>
<td></td>
<td></td>
<td>Loc 04</td>
<td></td>
<td></td>
<td></td>
<td>Loc 04</td>
</tr>
</tbody>
</table>

**CARDIOLOGY**

**Angiojet® Rheolytic™ Thrombectomy System for Coronary Interventions**

The Angiojet® Rheolytic™ Thrombectomy System has previously been approved by the Food and Drug Administration (FDA) for use in arteriovenous shunts and peripheral arteries. In March, 1999 the FDA approved the use of this system for the removal of thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels that are greater than or equal to 2.0 mm in diameter prior to balloon angioplasty or stent placement.

Florida Medicare considers the Angiojet® Rheolytic™ Thrombectomy System a covered service when used for the indications approved by the FDA. The provider performing the service for coronary interventions should bill using procedure code 93799 (unlisted cardiovascular service or procedure). The reimbursement for the thrombectomy is included in the reimbursement of the balloon angioplasty and/or stent placement performed on that patient.

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

**END-STAGE RENAL DISEASE**

**Intravenous Iron Therapy**

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing dialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hemocrit levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products.

The evidence suggests that there is little to distinguish various forms of IV iron therapy in terms of effectiveness. Rather, the medical literature indicates that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia. Review of medical literature indicated that the distinction among IV iron products lies within their safety profiles. The IV iron dextran products are associated with a small incidence of severe, life-threatening anaphylaxis. These type I hypersensitivity reactions, which are not dose-related, are immunoglobulin (Ig) E-mediated and are apparently exclusively associated with the dextran forms of injectable iron. In fact, clinical evidence indicates that the dextran component itself is what triggers the severe, life-threatening anaphylactic reactions. Sodium ferric gluconate complex in sucrose injection has demonstrated no life-threatening anaphylaxis and a less severe adverse-reaction rate when compared to iron dextran products.

Therefore, effective for services performed on or after December 1, 2000, Medicare covers sodium ferric gluconate complex in sucrose injection when used as a first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. The HCPCS code assigned to this service is J2915 (sodium ferric gluconate complex in sucrose injection, 62.5mg) effective for services rendered on or after January 1, 2001. For services rendered prior to January 1, providers should use code J3490 (unclassified drugs). Remember that anytime an unclassified drug is billed providers should ensure to indicate the name, strength, and dosage in block 19 of Form HCFA-1500 (or electronic equivalent).
Medicare allowances for influenza virus vaccines have been updated, effective for services processed on or after January 1, 2001. The new allowances are:

<table>
<thead>
<tr>
<th>CODE</th>
<th>ALLOWANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>90657</td>
<td>4.91</td>
</tr>
<tr>
<td>90658</td>
<td>6.70</td>
</tr>
<tr>
<td>90659</td>
<td>4.91</td>
</tr>
</tbody>
</table>

### New CLIA Waived Tests

Listed below are the latest tests approved by the Centers for Disease Control and Prevention (CDC) as waived tests under the Clinical Laboratory Improvement Amendments (CLIA). The Current Procedural Terminology (CPT) codes for these new tests must have the modifier QW to be recognized as a waived test.

**The following tests are effective for services processed on or after January 1, 2001:**

<table>
<thead>
<tr>
<th>TEST NAME</th>
<th>MANUFACTURER</th>
<th>CPT CODE(S)</th>
<th>USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>LifeSign Status H. pylori  (for wholeblood)</td>
<td>Princeton BioMeditech</td>
<td>86318QW</td>
<td>Immunoassay for rapid, qualitative detection of IgG antibodies specific to <em>Helicobacter pylori</em> in whole blood</td>
</tr>
<tr>
<td>Abbott Laboratories Medisense Products Precision™ Xtra™ Advanced Diabetes Management System</td>
<td>Abbott Laboratories, Inc.</td>
<td>82962, 82010QW</td>
<td>Monitoring of blood glucose levels and measures ketones in whole blood</td>
</tr>
<tr>
<td>PTS Bioscanner Test Strips Cholesterol</td>
<td>Polymer Technology Systems, Inc</td>
<td>82465QW</td>
<td>Cholesterol monitoring</td>
</tr>
<tr>
<td>Remel RIM7/A.R.C. H.pylori Test</td>
<td>Remel</td>
<td>86318QW</td>
<td>Immunoassay for rapid, qualitative detection of IgG antibodies specific to <em>Helicobacter pylori</em> in whole blood</td>
</tr>
<tr>
<td>LifeSign LLC Status Strep A Princeton</td>
<td>BioMeditech</td>
<td>87880QW</td>
<td>Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever</td>
</tr>
<tr>
<td>PTS, Inc. Bioscanner 2000 for Triglycerides</td>
<td>Polymer Technology Systems, Inc</td>
<td>84478QW</td>
<td>Measures triglycerides in whole blood</td>
</tr>
</tbody>
</table>

**The following tests are effective for services processed on or after April 1, 2001:**

<table>
<thead>
<tr>
<th>TEST NAME</th>
<th>MANUFACTURER</th>
<th>CPT CODE(S)</th>
<th>USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymedco, Inc. Poly stat H. pylori</td>
<td>Applied Biotech, Inc.</td>
<td>86318QW</td>
<td>Immunoassay for rapid, qualitative detection of IgG antibodies specific to <em>Helicobacter pylori</em> in whole blood</td>
</tr>
<tr>
<td>Polymedco, Inc. Poly stat Mono</td>
<td>Applied Biotech, Inc.</td>
<td>86308QW</td>
<td>Qualitative screening test for the presence of heterophile antibodies inhuman whole blood, which is used as an aid in the diagnosis of infectious mononucleosis</td>
</tr>
<tr>
<td>Polymedco, Inc. Poly stat A (II)</td>
<td>Applied Biotech, Inc.</td>
<td>87880QW</td>
<td>Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever</td>
</tr>
</tbody>
</table>
Trinity Uni-Gold™
H.pylori

Trinity BioTech

Trinity Technologies
Personnel Cholesterol Monitor

Lifetstream Technologies, Inc.

Teco Diagnostics URITEK
TC-101 Urine Strip Reader

Teco Diagnostics

Quidel QuickVue®
Influenza Test

Quidel Corporation

Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood.

Cholesterol monitoring

Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections

Qualitative detection of influenza type A and type B antigens from nasal swab, nasal wash or nasal aspirate specimens

The complete list of waived tests is available on the Health Care Financing Administration’s Website, http://www.hcfa.gov/medicaid/clia/cliahome.htm.

2001 Clinical Laboratory Fee Schedule Allowances for Pap Smears

The 2001 Clinical Laboratory Fee Schedule allowances were provided in the December 2000 Special Issue *Medicare B Update!* (pages 52-55). Since release of that publication, the fees for codes P3000, 88150, 88152, 88153, 88154, 88164, 88165, 88166, and 88167 have been updated to $14.60, effective for services rendered on and after January 1, 2001.

**MEDICARE PHYSICIAN FEE SCHEDULE**

Changes to the 2001 Medicare Fee Schedule

The Health Care Financing Administration’s (HCFA) Division of Practitioner and Ambulatory Care has identified several inconsistencies in the 2001 Medicare Physician Fee Schedule Database (MPFSDB). These changes, described below, are effective for services rendered on or after January 1, 2001.

For the following HCPCS procedures, the status code has changed from “D” (deleted/discontinued code subject to a 90-day grace period) to “I” (code is not valid for Medicare purposes; code is not subject to a 90 day grace period).


For HCPCS code A0225 the status indicator has changed from “X” (Statutory exclusion. Codes represent an item or service that is not in the statutory definition of “physician services” for fee schedule payment purposes) to “D.”

For HCPCS codes A0380 and A0390 the status indicator changed from “D” to “X.”

For HCPCS codes G0195 and G0196, the status indicator changed from “C” (Carrier Priced) to “A” (Active).

For CPT codes 52352, 52355 the bilateral surgical indicator changed from “0” (150% payment adjustment does not apply) to “1” (150% payment adjustment does apply)

For the following CPT codes, adjustments have been made to the Relative Value units, resulting in the Fee Schedule amounts being changed:

For **PAR** codes 52352, 52355 the bilateral surgical indicator changed from “0” (150% payment adjustment does not apply) to “1” (150% payment adjustment does apply)

For the following **PAR** codes, adjustments have been made to the Relative Value units, resulting in the Fee Schedule amounts being changed:

* these amounts apply when performed in a facility setting
For the following CPT codes, the status indicator changed from “A” to “D.”
76934, 76934-TC, 76934-26, 76938, 76938-TC, 76938-26, 76960, 76960-TC, 76960-26, 87145, 87208

For CPT codes 92525, 92597, 92598, 99375, and 99378 the status indicator changed from “N” (noncovered service) to “G” (not valid for Medicare purposes, code subject to a 90 day grace period). The fees listed below for these services are valid only through March 31, 2001.

<table>
<thead>
<tr>
<th>CODE</th>
<th>PAR Loc 01/02</th>
<th>Loc 03</th>
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<th>Loc 04</th>
<th>LC Loc 01/02</th>
<th>Loc 03</th>
<th>Loc 04</th>
</tr>
</thead>
<tbody>
<tr>
<td>92525</td>
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For CPT code 93662, the PC/TC-indicator changed from “1” (diagnostic test having both a technical and professional component) to “2” (professional component only). The Fee Schedule amounts for CPT codes 93662-TC and 93662-26 have been deleted because of this reclassification.

* these amounts apply when performed in a facility setting

### 2001 Carrier-Priced Fee Schedule Services

The following carrier-priced fee schedule services (pricing calculated by the local carrier) were not included in the 2001 Medicare Part B Physician and Non-Physician Fee Schedule because the information needed to determine allowances and/or coverage was not yet available at the time the book was produced.

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* these amounts apply when performed in a facility setting
Intestinal Transplantation

Effective for services performed on or after April 1, 2001, Medicare covers intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity. This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria. TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. Failed TPN for liver failure, thrombosis, frequency of infection, and dehydration are indicated in the following clinical situations:

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
- Thrombosis of the major central venous channels: jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, superior vena cava syndrome, or chronic venous insufficiency.
- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreaticobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Intestinal transplantation may be covered by Medicare if performed in an approved facility. Medicare will not pay a separate cost for organ acquisition to transplant facilities. Immunosuppressive therapy for intestinal transplantation is covered. As with all Medicare claims, submitting a diagnosis is required; however, there is no specific ICD-9-CM diagnosis code for intestinal failure, although diagnosis codes exist to capture the causes of intestinal failure. Some examples of intestinal failure include, but are not limited to:

- Volvulus 560.2
- Volvulus gastrochisis 756.79, other [congenital] anomalies of abdominal wall
- Volvulus gastrochisis 569.89, other specified disorders of intestine
- Necrotizing enterocolitis 777.5, necrotizing enterocolitis in fetus or newborn
- Necrotizing enterocolitis 014.8, other tuberculosis of intestines, peritoneum, and mesenteric glands
- Necrotizing enterocolitis and splanchnic vascular thrombosis 557.0, acute vascular insufficiency of intestine
- Inflammatory bowel disease 569.9, unspecified disorder of intestine
- Radiation enteritis 777.5, necrotizing enterocolitis in fetus or newborn
- Radiation enteritis 558.1

Effective for services performed on or after April 1, 2001, physicians should enter the following CPT codes for intestinal transplantation in block 24D of the form HCFA 1500 (or electronic equivalent):

44132* Donor enterectomy, open, with preparation and maintenance of allograft; from cadaver donor
44133 partial, from living donor
44135 Intestinal allotransplantation; from cadaver donor
44136 Intestinal allotransplantation; from living

*NOTE: CPT code 44132 is not paid by carriers and will be denied if billed. Payment for this code is made by the intermediary to the facility where the organ is procured.

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Cryosurgery of the Prostate Gland: New CPT Code

The American Medical Association’s (AMA) *Current Procedural Terminology* (CPT) for 2001 establishes a new code for cryosurgery of the prostate gland and its accompanying ultrasonic guidance:

55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)

This new code includes both the cryosurgical ablation procedure and the ultrasonic guidance for interstitial cryosurgical probe placement. Effective January 1, 2001, it replaces the previous two HCPCS codes G0160 and G0161. Providers may continue to use G0160 and G0161 codes for claims with dates of service January 1 through March 31, 2001 that are received on or before April 1, 2001.

Because the new code includes payment for both procedures, Medicare will not pay separately for the ultrasonic guidance when CPT code 55873 is used in situations where one provider has provided the cryosurgical ablation and another has provided the ultrasonic guidance for the same beneficiary for the same date of service. In these instances, the provider of the cryosurgical ablation must submit the claim, and the provider of the ultrasonic guidance should seek compensation from the provider of the cryosurgical ablation.

For more information concerning cryosurgical ablation of the prostate, refer to Florida Medicare’s local medical review policy (LMRP) found on pages 53-54.

**VISION CARE**

Ocular Photodynamic Therapy

Information concerning Ocular Photodynamic Therapy (OPT) was published in the 1st Quarter 2001 *Medicare B Update!* (page 16). Since then, the 2001 HCPCS update has provided additional information concerning the appropriate method of billing for OPT.

Effective for services performed on and after January 1, 2001, CPT code 67221 [destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion)] should not be used for a second procedure performed (i.e., on the second eye) on the same beneficiary on the same day. HCPCS code G0184 [destruction of localized lesion of choroid (for example, choroidal neovascularization); ocular photodynamic therapy (includes intravenous other eye)] should be used for the second eye. Additionally, both 67221 and G0184 should be billed with the right or left modifier (RT or LT) as appropriate, to prevent duplicate denials.

For more information, please see pages 61-64 for Florida Medicare’s local medical review policy for OPT.
This section of the Medicare B Update! features new and revised medical policies developed as a result of either the Local Medical Review (LMR) or Focused Medical Review (FMR) initiatives. Both initiatives are designed to ensure the appropriateness of medical care and that the carrier’s medical policies and review guidelines are consistent with the accepted standards of medical practice.

LMRP Format
The LMRP format is consistent with the manner in which the carrier reports LMRPs to the Health Care Financing Administration (HCFA).

Effective Dates
The effective dates are provided in each policy. Effective dates are based on the date claims are processed, not the date of service (unless otherwise noted in the policy).

More Information
Draft LMRPs and previously published final LMRPs may be obtained by accessing the Florida Medicare provider website through the First Coast Service Options Medicare gateway at: www.FCSOMedicare.com

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The Health Care Financing Administration (HCFA) and the AMA recently signed an amendment to the original 1983 Agreement on HCFA’s use of CPT coding. This new amendment covers the use of CPT codes, descriptions, and other materials on contractors’ Web sites and in other electronic media. The amendment specifies that contractors refrain from publishing lists containing CPT long descriptors, if such lists comprise more than 30 percent of a section or subsection of the current CPT book.

Florida Medicare provides electronic copies of printed publications (such as the Medicare B Update!) on our provider Web site exactly as they were produced in hard copy format. This assures that publications downloaded from the Web have the same content as the hard copies that were mailed. In order to maintain this consistency, beginning with this issue long descriptors for both CPT and HCPCS codes will generally no longer be provided in the CPT/HCPCS sections of local medical review policies. Additionally, descriptions for ICD-9-CM diagnosis codes will no longer be published; only the codes. In the event that a complete description of a service or diagnosis is necessary for proper understanding of a policy or section of a policy, however, such descriptions will be included.

The rationale behind this change is the requirement in the copyright agreement that publications must be designed to convey Medicare specific information and not CPT coding advice. Publications must not be designed to substitute for the CPT book with respect to codes, long descriptions, notes, or guidelines for any user.

Acquiring the 2001 Coding Books

Providers are strongly encouraged to purchase the 2001 Current Procedural Terminology (Level I) book. The 2001 edition of the CPT (Level I codes) may be purchased from the American Medical Association by calling (800) 621-8335, or by writing to:

- American Medical Association
- P.O. Box 109050
- Chicago, IL 60610-0946

The 2001 CPT book is also available in electronic format. Additionally, it may be ordered online from the AMA’s CPT home page at: http://www.ama-assn.org/med-sci/cpt/coding.htm. For more information, call the toll-free number listed above.

The 2001 HCPCS Alpha-Numeric Hardcopy

The 2001 alpha-numeric hardcopy, titled 2001 Alpha-Numeric HCFA Common Procedure Coding System (the HCPCS Level II coding book) is also recommended. It may be secured from:

- Superintendent of Documents
- U.S. Government Printing Office
- Washington D.C. 20402
- Telephone: (202) 512-1800

The 2001 ICD-9-CM Book

The latest versions of the International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) manual (as well as a variety of other coding materials) may be obtained from:

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<th>HealthCare Consultants of America</th>
<th>Medicoce Publications</th>
<th>St. Anthony’s Publishing</th>
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<td>(800) 253-4945</td>
<td>(800) 999-4600</td>
<td>(800) 632-0123</td>
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ICD-9-CM and other coding materials may also be obtained from local medical publishing and consulting firms.

A9270: The List of Medicare Noncovered Services

The List of Medicare Noncovered Services (policy number A9270) was published in the March/April 2000 Medicare B Update! (pages 19-23). The annual HCPCS update for 2001 requires the following changes, effective for services rendered on or after January 1, 2001 (except where otherwise noted):

* Denotes services that are noncovered due to their being investigational/experimental.

Additions to Local Noncoverage Decisions

Laboratory Procedures

A9270 Homocystine testing for cardiovascular screening

NOTE: CPT code 83090 (Homocystine) has been deleted from noncoverage - homocystine testing is noncovered only when performed for cardiovascular screening. Use A9270 for homocystine testing for cardiovascular screening.

86301* Immunoassay for tumor antigen, quantitative; CA 19-9
86316* Immunoassay for tumor antigen; other antigen, quantitative (eg, CA 50, 72-4, 549), each
87081 Culture, presumptive, pathogenic organisms, screening only;
87084 with colony estimation from density chart
### Local and Focused Medical Review Policies

#### Revisions to Local Noncoverage Decisions Due to Descriptor Changes

**Procedures**

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<th>Code</th>
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<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
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#### Revisions to National Noncoverage Decisions Due to Descriptor Changes

**Drugs and Biologicals**

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<tr>
<td>90669</td>
<td>Pneumococcal conjugate vaccine, polyvalent, for children under five years, for intramuscular use</td>
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#### Deletions from National Noncoverage Decisions

Effective for services rendered on or after January 1, 2001, the following services have been removed from national noncoverage due to a change in their status on the Medicare Physician Fee Schedule Database (MPFSDDB). They are now listed as "not valid for Medicare purposes:"

**Procedures**

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<td>Evaluation of swallowing and oral function for feeding (MCM 2070)</td>
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<td>92597</td>
<td>Evaluation for use and/or fitting of voice prosthetic or augmentative/alternative communication device to supplement oral speech</td>
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<td>92598</td>
<td>Modification of voice prosthetic or augmentative/alternative communication device to supplement oral speech</td>
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<td>99375</td>
<td>Physician supervision of a patient under care of home health agency (patient not present) in home, domiciliary or equivalent environment (eg, Alzheimer’s facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with other health care professionals and other non-physician professionals involved in patient’s care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more</td>
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<td>99378</td>
<td>Physician supervision of a hospice patient (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of</td>
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patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with other health care professionals and other non-physician professionals involved in patient’s care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 30 minutes or more.

Deletion from Local Noncoverage Decisions Effective March 19, 2001

In addition to the preceding changes required by the 2001 HCPCS update, CPT code 62263 is being removed from local noncoverage, effective for services processed on or after March 19, 2001. For more information, refer to the local medical review policy for Percutaneous Lysis Of Epidural Adhesions on pages 55-56 of this issue.

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For further information regarding The List of Medicare Noncovered Services, please refer to the “ICD-9-CM Codes that Support Medical Necessity,” “Reasons for Denial”, “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the March/April 2000 Update!

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Medical Policy Procedures: G0108

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<td>CPT codes, descriptions, and other data only are copyright 1998 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Apply.</td>
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Diabetes mellitus is a chronic disorder of carbohydrate, fat and protein metabolism, characterized by hyperglycemia and glycosuria from inadequate production or utilization of insulin. The diagnosis of Diabetes mellitus is made based on the test results of a random plasma glucose greater than 200 mg/dl, fasting plasma (8-14 hours) greater than or equal to 126 mg/dl on two occasions, or a two hour plasma glucose greater than 200 mg/dl after a 75 gm glucose challenge.

Diabetes mellitus is classified according to two syndromes: Type 1 diabetes and Type 2 diabetes. Type 1 diabetes is characterized by beta cell destruction, usually leading to absolute insulin deficiency. It has two forms: Immune-Mediated Diabetes Mellitus and Idiopathic Diabetes Mellitus. Type 1 diabetes is usually immune-mediated. Type 2 diabetes is a term for individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency.

Since diabetes is a chronic illness, the patient requires continual medical care and education in order to prevent acute complications and reduce the risk of long-term medical problems. A critical element for the successful treatment of all patients with diabetes is participation in a comprehensive self-management care and education program. Ongoing support, maintenance, and modifications in treatment regimes and lifestyle changes all require continued patient and caregiver participation.

A diabetes outpatient self-management training service is a program that educates beneficiaries in the successful self-management of diabetes. An outpatient diabetes self-management and training program includes education about self-monitoring of blood glucose, diet and exercise, an insulin treatment plan developed specifically for the patient who is insulin-dependent, and it motivates patients to use the skills for self-management.

This policy addresses Medicare’s coverage of diabetes outpatient self-management training services based on section 4105 of the Balanced Budget Act of 1997.
Local and Focused Medical Review Policies

Indications and Limitations of Coverage and/or Medical Necessity
Prior to July 1, 1998, Medicare provided additional reimbursement for diabetic education programs when performed in an outpatient hospital and met certain criteria outlined in Section 80-2 of the Coverage Issues Manual (CIM). Since that time further legislation regarding coverage of outpatient diabetic education has been received and is identified below.

Medicare will consider diabetes outpatient self-management training services medically reasonable and necessary for services performed on or after July 1, 1998 when the following conditions are met:

- The services are furnished by a certified provider who meets quality standards as identified by the National Diabetes Advisory Board (NDAB). To be considered a quality diabetes self-management education program, the program must provide comprehensive instruction in the content areas that impact the target population and the participants enrolled. Standard 12 of the NDAB standards identifies the 15 content areas. The curriculum, teaching strategies, and materials used should be appropriate for the audience and should consider: type and duration of diabetes, age, cultural sensitivity, and individual learning abilities and special educational needs. The NDAB standards are listed herein, beginning in the next column.

- Education is provided by a program that is recognized by the American Diabetes Association. This is indicated by an Education Recognition Program (ERP) certificate administered through the American Diabetes Association.

- The physician who is managing the beneficiary’s diabetic condition certifies that such services are needed under a comprehensive plan of care. This plan of care must be related to the beneficiary’s diabetic condition to ensure therapy compliance, or to provide the individual with the necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to successfully manage his/her condition.

During the initial period of onset of the disease, diabetes self-management education is critical to the treatment and management of the illness and should be introduced within the first week of diagnosis. Normally, as a general guideline, it would not be medically necessary for a beneficiary to receive more than 10 hours of instruction for the initial training. This training should be provided within 12 weeks of the initial diagnosis. In addition, diabetes self-management training normally occurs in group sessions. However, individual training sessions may be provided for a beneficiary if his/her physician decides that it is medically necessary (e.g., language or physical challenges, such as severely impaired hearing or sight).

Self-management education starts with an assessment of the individual’s educational needs that will assist in the planning of teaching/learning strategies and will be the foundation of an education and lifestyle plan. Patient outcomes will be monitored for lifestyle changes and revised as necessary.

After completion of the initial self-management diabetes training, ongoing support and maintenance should be provided by the beneficiary’s physician and/or support system. Additional self-management education training sessions may be necessary in situations where a modification has occurred in the treatment regime (e.g., a change from oral medications to insulin, inability to stabilize patient, etc.). Training sessions performed as a refresher course (e.g., annually) without documentation supporting a change in the treatment regime are not covered.

The National Diabetes Advisory Board (NDAB) standards are:

I. STRUCTURAL STANDARDS

A. Organizational support by sponsoring organization

Standard 1: Maintain written policy affirming education as an integral component of diabetes care.

Standard 2: Provide education resources needed to achieve objectives for target population, including adequate space, personnel, budget and instructional materials.

Standard 3: Clearly define and document organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

B. Community needs assessment

Standard 4: Assess service area to define target population and determine appropriate allocation of personnel and resources.

C. Program management

Standard 5: Establish standing advisory committee including at least a physician, nurse educator, dietitian, behavioral science expert, consumer, and community representative to oversee the program.

Standard 6: The advisory committee should participate in annual planning to determine target population, program objectives, participant access, and follow-up mechanisms, instructional methods, resource requirements, and program evaluation.

Standard 7: Professional program staff should have sufficient time and resources for lesson planning, instruction, documentation, evaluation, and follow-up.

Standard 8: Assess community resources periodically.

D. Program staff

Standard 9: Designate a coordinator responsible for program planning, implementation, and evaluation.

Standard 10: Program instructors should include at least a nurse educator and dietitian with recent didactic and experiential training in diabetes clinical and educational issues.

Standard 11: Professional program staff should obtain continuing education about diabetes, educational principles, and behavioral change strategies.
E. Curriculum
Standard 12: The program must be capable of offering, based on target population needs, instruction in the following 15 content areas:

- diabetes overview
- stress and psychosocial adjustment
- family involvement and social support
- nutrition
- exercise and activity
- medications
- monitoring and use of results
- relationships among nutrition, exercise, medication, and glucose levels
- prevention, detection and treatment of acute complications
- prevention, detection and treatment of chronic complications
- foot, skin, and dental care
- behavior change strategies, goal setting, risk factor reduction, and problem solving
- benefits, risks and management options for improving glucose control
- preconception care, pregnancy, and gestational diabetes
- use of health care systems and community resources

Standard 13: Use instructional methods and materials appropriate for the target population.

F. Participant Access
Standard 14: Establish a system to inform the target population and potential referral sources of availability and benefits of the program.

Standard 15: The program must be conveniently and regularly available.

Standard 16: The program must be responsive to requests for information and referrals from consumers, health professionals, and health agencies.

II. PROCESS STANDARDS
A. Assessment
Standard 17: Develop and update an individualized assessment for each participant, including medical history and health status; health services utilization; risk factors; diabetes knowledge and skills; cultural influences; health beliefs, attitudes, behavior and goals; support systems; barrier to learning; and socioeconomic factors.

B. Plan and Implementation
Standard 18: Develop an individualized education plan, based on the individualized assessment, in collaboration with each participant.

Standard 19: Document the assessment, intervention, evaluation, and follow-up for each participant, and collaboration and coordination among program staff and other providers, in a permanent record.

C. Follow-up
Standard 20: Offer appropriate and timely educational intervention based on periodic assessments of health status, knowledge, skills, attitude, goals, and self-care behaviors.

III. OUTCOME STANDARDS
A. Program
Standard 21: The advisory committee should review program performance annually, and use the results in subsequent planning and program modification.

B. Participant
Standard 22: The advisory committee should annually review and evaluate predetermined outcomes for program participants.

HCPCS Section & Benefit Category
Medicine

HCPCS Codes
G0108 Diabetes outpatient self-management training services, individual, per 30 minutes
G0109 Diabetes outpatient self-management training services, group session 2 or more, per 30 minutes

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
250.00-250.93

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Diabetic self-management training performed as a refresher course without a change in the patient’s treatment regime is not covered.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
Prior to billing for diabetes outpatient self-management training services, all providers must submit to the Medicare contractor an Education Recognition Program (ERP) certificate from the American Diabetes Association.
Services for diabetes outpatient self-management training must be billed with the appropriate HCPCS code, G0108 or G0109, in 30 minute increments only. If the training session lasts 45 minutes, only 30 minutes can be billed for that session. The extra 15 minutes may count toward future sessions.

The number of patients in a group does not need to be identified when billing for procedure code G0109.

Payment for diabetes outpatient self-management training services rendered in a Federal Qualified Health Center (FQHC) or a Rural Health Center (RHC) setting by a nonphysician practitioner is bundled under the facility cost payment that is made by the intermediary under the all inclusive rate.

**Documentation Requirements**

In order for diabetic self-management training sessions to be covered by Medicare, documentation must be available to support that the educational program is certified by the American Diabetes Association as evidenced by the Education Recognition Program (ECP) certificate.

In addition to the above requirement, the following documentation must be maintained in the patient’s medical record:

- A physician order, referral, or attestation for the diabetic self-management training sessions. This order must certify that the beneficiary’s diabetic condition warrants this comprehensive plan of care.
- An individualized assessment with updated information including medical history and health status; health services utilization; risk factors; diabetes knowledge and skills; cultural influences; health beliefs, attitudes, behavior and goals; support systems; barrier to learning; and socioeconomic factors.
- An individualized mutually agreed upon education plan established by the team (patient, physician, and health care team members) based on the individualized assessment, including but not limited to the specific problems to be addressed, specific educational modalities, specific goals of the educational session, and the amount, frequency, and duration of each educational modality.
- Documentation (e.g., progress notes) for each date of service that reflect the service(s) provided and instruction given. In addition, the documentation should indicate the patient’s response to the service and the progress toward the goals. The daily note must be signed and dated by the qualified team member who rendered the service.
- Documentation supporting the continuation of the diabetic self-management training session beyond the expected 10 hours during the initial phase must be available. In addition, repeat sessions during the follow-up phase must indicate the patient’s treatment regime has changed and that additional training sessions are needed to educate the patient for continual self-management of the disease.

Also, since diabetes self-management training normally occurs in group sessions, the documentation maintained on file must be available to support the medical necessity for performing individual training sessions.

**Utilization Guidelines**

N/A

**Other Comments**

Terms defined:

Certified provider - physicians, individuals or entities that are paid under the physician-fee schedule. This includes the following non-physician practitioners: physician assistants (PAs), nurse practitioner (NPs), nurse midwives (NMs), clinical psychologists (CPs), and clinical social workers (CSWs).

Glycosuria - the presence of glucose in the urine. Traces of sugar, particularly glucose, may occur in normal urine but are not detected by ordinary qualitative methods. In routine urinalyses the presence of a reducing sugar is suspicious of diabetes mellitus.

**Sources of Information**

Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

**Advisory Committee Notes**

This policy does not reflect the sole opinion of the carrier or the Carrier Medical Director. Although the final decision rests with the carrier, this policy was developed in cooperation with the Carrier Advisory Committee which includes representatives from numerous societies.

**Start Date of Comment Period**

N/A

**Start Date of Notice Period**

02/01/2001

**Revision History**

Revision Number: 1  PCR B2001-043
Start Date of Comment Period:  N/A
Start Date of Notice Period:  02/01/2001

2nd Qtr 2001 Update!

Revised Effective Date:  01/01/2001
Explanation of Revision:  Annual 2001 HCPCS update

**Advance Notice Statement**

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Medical Policy Procedures: J1950

The LMRP for Leuprolide Acetate (policy number J1950) was published in the July/August 2000 Medicare B Update! (pages 33-36). The annual HCPCS update for 2001 adds an additional procedure code to this policy:

J9219 Leuprolide acetate implant, 65 mg

All requirements listed in the policy apply to this new HCPCS code. For specific information, please refer to the “ICD-9-CM Codes that Support Medical Necessity,” “Coding Guidelines,” “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the July/August 2000 Update!

Medical Policy Procedures: J7190

The LMRP for Hemophilia Clotting Factors (policy number J7190) was published in the May/June 2000 Medicare B Update! (pages 17-19). The annual HCPCS update for 2001 adds an additional procedure code to this policy:

Q2022 von Willebrand factor complex, human, per IU

All requirements listed in the policy apply to this new HCPCS code. For specific information, please refer to the “ICD-9-CM Codes that Support Medical Necessity,” “Coding Guidelines,” “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the May/June 2000 Update!

Medical Policy Procedures: J9999

Policy Number
J9999

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Antineoplastic Drugs

AMA CPT Copyright Statement
CPT codes, descriptions, and other data only are copyright 2000 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.

HCFA National Coverage Policy
Medicare Carriers Manual, Section 2049

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
12/12/1997

Revision Effective Date
02/02/2001

Revision Ending Effective Date
02/04/2000

Policy Ending Date
N/A

LMRP Description
According to Medicare guidelines, certain medical services which are deemed reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are covered services. FDA approval is often one of the main criteria of Medicare’s coverage guidelines for drugs and biologicals. However, in the case of chemotherapeutic agents, FDA approval does not always keep pace with clinically indicated efficacy. Therefore, the need exists to address off-label chemotherapy drug uses which have been validated by clinical trials.

The purpose of this policy is to establish the FDA approved indications of antineoplastic drugs and to indicate the circumstances under which Medicare will consider off-label uses for chemotherapy drugs to be medically reasonable and necessary, and to specify those drugs and their FDA approved and off-label uses as they become available. This policy does not restrict what providers can provide nor what beneficiaries receive. It simply defines what can be covered by Medicare in order to avoid or reduce denials for unapproved treatment.

Indications and Limitations of Coverage and/ or Medical Necessity

For off-label use:
Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used singly or in an anti-cancer regimen for a medically accepted indication are evaluated under the conditions described in the following paragraphs. A regimen is a combination of anti-cancer agents which have been clinically recognized for the treatment of a specific type of cancer. An example of a drug regimen is: Cyclophosphamide + Vincristine + Prednisone (CPV) for non-Hodgkin’s lymphoma. There may be different regimens or combinations which are used at different phases of the cancer’s history (induction, prophylaxis of CNS involvement, post remission, and relapsed or refractory disease). A protocol may specify the combination of drugs, doses, and schedules for administration of the drugs. For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the treatment regimen when the drugs are administered incident to a chemotherapy treatment.
To evaluate the off-label uses of chemotherapeutic agents for coverage, the uses must not be listed as “not indicated” by HCFA, the FDA, or the compendia. Justification for approval of off-label uses must be based upon data from clinical trials in which there was a defined combination and dosage schedule, an appropriate study design, an adequate number of trial subjects, and evidence of significant increase in survival rate or life expectancy or an objective and significant decrease in tumor size or reduction in tumor-related symptoms. 

The unlabeled uses of a chemotherapy drug must be supported by one of the following:

- The compendia. (If an unlabeled use does not appear in the compendia or is listed there as insufficient data or investigational, the compendia will be contacted to determine whether a report is forthcoming. If a report is forthcoming, the information in that report will be used as a basis for decision making. The compendium process for making decisions regarding unlabeled uses is very thorough and continually updated).
- Phase III clinical trials.
- Clinical research that appears in peer reviewed medical literature. This includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).
- Use peer-reviewed medical literature appearing in the following publications:
  - American Journal of Medicine; 
  - Annals of Internal Medicine; 
  - The Journal of the American Medical Association; 
  - Journal of Clinical Oncology; 
  - Blood; 
  - Journal of the National Cancer Institute; 
  - The New England Journal of Medicine; 
  - British Journal of Cancer; 
  - British Journal of Hematology; 
  - British Medical Journal; 
  - Cancer; 
  - Drugs; 
  - European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); 
  - Lancet; or 
  - Leukemia.

The carrier is not required to maintain copies of these publications. Physicians seeking to establish Medicare coverage for specific off-label uses of chemotherapeutic drugs must submit documentation from any of the above publications supporting the efficacy of each of the off-label uses to the Medicare Medical Policy and Procedures Department.

Following are chemotherapy drugs and their FDA approved and off-label uses for which Florida Medicare considers coverage to be medically reasonable and necessary:

**Doxorubicin HCL 10mg (Adriamycin PFS; Adriamycin RDF; Rubex)-J9000**

Doxorubicin is an anthracycline glycoside; it is classified as an antibiotic but is not used as an antimicrobial agent. It selectively kills malignant cells and produces tumor regression in a variety of human neoplasms.

Doxorubicin may be administered intravenously, intra-arterially, and as a topical bladder instillation.

Doxorubicin is FDA approved for treatment of the following medical conditions:


Florida Medicare will cover Doxorubicin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Cervical carcinoma
- Endometrial carcinoma
- Head and neck carcinoma
- Non-small cell lung carcinoma
- Pancreatic carcinoma
- Prostatic carcinoma
- Ovarian germ cell tumors
- Ewing’s sarcoma
- Multiple myeloma
- Chronic lymphocytic leukemia
- Primary hepatocellular carcinoma
- Hepatoblastoma
- Thymoma
- Gestational trophoblastic tumors
- AIDS related Kaposi’s sarcoma
- Retinoblastoma
- Esophageal carcinoma
- Adrenocortical carcinoma

**Doxorubicin, Liposomal (Doxil)-J9001**

Doxorubicin is an anthracycline cytotoxic antibiotic. Liposomal Doxorubicin is Doxorubicin encapsulated in long-circulating liposomes. Liposomes are microscopic vesicles composed of a phospholipid bilayer that are capable of encapsulating active drugs. Once within the tumor, the active ingredient Doxorubicin is presumably available to be released locally as the liposomes degrade and become permeable in situ.

Liposomal Doxorubicin is FDA approved for the following medical conditions:

- AIDS-related Kaposi’s sarcoma disease that has progressed in spite of prior combination chemotherapy or patients who are intolerant of such therapy.
- Metastatic carcinoma of the ovary that is refractory to treatment.

Florida Medicare will cover Liposomal Doxorubicin for its FDA approved uses, as well as for the treatment of the off-labeled indication, breast carcinoma.
Aldesleukin (Proleukin®, interleukin-2, recombinant, and rIL-2)-J9015
Aldesleukin is classified as a biological response modifier. It increases cellular immunity and inhibits tumor growth. Because of its potential life-threatening toxicities, it is recommended that this medication be given only after careful consideration of the risks and benefits.
Aldesleukin is FDA approved for treatment of renal carcinoma and metastatic melanoma.
Florida Medicare will cover Aldesleukin for its FDA approved uses, as well as for the off-labeled indication, chronic myelogenous leukemia.

Carboplatin (Paraplatin®, Paraplatin-AQ®)-J9045
Carboplatin resembles an alkylating agent. Although the exact mechanism of action is unknown, it is thought to be similar to that of the bifunctional alkylating agents, that is, possible cross-linking and interference with the function of DNA.
Carboplatin is FDA approved for the treatment of ovarian carcinoma, when refractive to standard chemotherapy that did or did not include Cisplatin and for the initial treatment of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents.
Florida Medicare will cover Carboplatin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Bladder carcinoma
- Primary brain tumors
- Breast carcinoma
- Endometrial carcinoma
- Head & neck carcinoma
- Small cell and non-small cell lung carcinoma
- Malignant melanoma
- Neuroblastoma
- Retinoblastoma
- Testicular carcinoma
- Wilms’ Tumor
- Esophageal carcinoma
- Cervical carcinoma
- Cancer of Unknown Primary site (CUPs)

Docetaxel (Taxotere®)-J9170
Docetaxel, an antineoplastic agent belonging to the taxoid family, acts by disrupting cell replication. It is a derivative of 10-deacetylbaccatin 111, a compound extracted from the needles of the European yew tree. Docetaxel acts by disrupting the microtubular network in cells, an essential component of vital mitotic and interphase cellular functions.
Taxotere is FDA approved in the treatment of breast cancer, as a second-line treatment of AIDS-related Kaposi’s sarcoma, and for the treatment of cisplatin-resistant, non-small cell lung cancer.
Florida Medicare will cover Taxotere for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Small cell carcinoma of the lung
- Head and neck carcinoma
- Bladder carcinoma
- Ovarian carcinoma
- Gastric carcinoma
- Melanoma
- Prostatic carcinoma

Etoposide (Etopophos®, Toposar®, VePesid®, VP-16)-J9181 & J9182
Etoposide is a podophyllotoxin which inhibits DNA synthesis prior to mitosis by blocking topoisomerase II.
Etoposide is FDA approved for the treatment of testicular carcinoma and small cell lung carcinoma.
Florida Medicare will cover Etoposide for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Gastric carcinoma
- Hepatoblastoma
- Neuroblastoma
- Non-small cell lung carcinoma
- Thymoma
- Osteosarcoma
- Ewing’s sarcoma
- Soft tissue sarcomas
- Cutaneous T cell lymphomas
- Breast carcinoma
- Kaposi’s sarcoma
- Endometrial carcinoma
- Ovarian carcinoma
- Bladder carcinoma
- Wilms’ Tumor
- Retinoblastoma
- Adrenocortical carcinoma
- Acute lymphocytic leukemia
- Acute nonlymphocytic leukemia
- Chronic myelocytic leukemia
- Hodgkin’s lymphoma
- Non-Hodgkin’s lymphoma
- Multiple myeloma
- Primary brain tumor
- Gestational trophoblastic tumor
- Cancer of Unknown Primary site (CUPs)

Fludarabine (Fludara®)-J9185
Fludarabine phosphate is a nucleotide analog which is incorporated into DNA and inhibits further DNA synthesis.
Fludarabine is FDA approved for treatment of chronic lymphocytic leukemia.
Florida Medicare will cover Fludarabine for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Acute Non-Lymphocytic Leukemia
- Non-Hodgkin’s Lymphoma

Gemcitabine (Gemzar®)-J9201
Gemcitabine is a deoxycytidine analogue antimetabolite which is structurally related to cytarabine. In contrast to cytarabine, it has greater membrane permeability and enzyme affinity, as well as prolonged intracellular retention. The compound acts as an inhibitor of DNA synthesis, and its mechanism of action appears to be cell-cycle specific.
Gemzar is FDA approved for treatment of patients with advanced or metastatic adenocarcinoma of the pancreas and non-small cell lung cancer.
Florida Medicare will cover Gemzar for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Breast carcinoma
- Ovarian carcinoma
- Bladder carcinoma
- Transitional cell carcinoma of kidney and ureter
LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

Irinotecan (Camptosar®)-J9206
Irinotecan, also known as CPT-11, is an analog of camptothecin, a plant alkaloid. It inhibits the enzyme, topoisomerase I, which is necessary for DNA replication. Irinotecan is FDA approved for the treatment of colorectal carcinoma.

Florida Medicare will cover Irinotecan for its FDA approved use, as well as for the treatment of the following off-labeled indications:

- Small-cell lung carcinoma
- Cervical carcinoma

Paclitaxel (Taxol®)-J9265
Paclitaxel is an antimitotubule agent. It interferes with the normal cellular microtubule function that is required for interphase and mitosis.

Paclitaxel is FDA approved for treatment of the following medical conditions:

Breast carcinoma after failure of combination chemotherapy or at relapse within 6 months of adjuvant chemotherapy; advanced carcinoma of ovary; as a second-line treatment for AIDS-associated Kaposi’s sarcoma; and non-small cell lung carcinoma in combination with Cisplatin as a first-line treatment for patients who are not candidates for radiation therapy or potentially curative surgery.

Florida Medicare will cover Paclitaxel for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Bladder carcinoma
- Cervical carcinoma
- Endometrial carcinoma
- Esophageal carcinoma
- Head & neck carcinoma
- Small cell lung carcinoma
- Prostate carcinoma
- Gastric carcinoma
- Malignant pleural effusion
- Cancer of Unknown Primary site (CUPs)

Mitomycin (Mutamycin®, mitomycin-C)-J9280, J9290 & J9291
Mitomycin is classified as an antitumor antibiotic. It inhibits DNA synthesis by causing cross-linking. It also inhibits RNA and protein synthesis.

Mitomycin concentrate may be used intravenously or as a topical bladder instillation.

Mitomycin is FDA approved for treatment of gastric and pancreatic carcinoma.

Florida Medicare will cover Mitomycin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Bladder carcinoma
- Cervical carcinoma
- Breast carcinoma
- Esophageal carcinoma
- Head & neck carcinoma
- Non-small cell lung carcinoma
- Prostatic carcinoma
- Gallbladder & biliary carcinoma
- Colorectal & anal carcinoma
- Chronic myelocytic & myelomonocytic leukemias

Mitoxantrone Hydrochloride (Novantrone®)-J9293
Mitoxantrone hydrochloride is an anthracenedione which inhibits DNA and RNA synthesis.

Mitoxantrone hydrochloride is FDA approved for treatment of advanced symptomatic prostate carcinoma and acute non-lymphocytic leukemia.

Florida Medicare will cover Mitoxantrone hydrochloride for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Breast carcinoma
- Acute lymphocytic Leukemia
- Non-Hodgkin’s Lymphoma

Topotecan Hydrochloride (Hycamtin®)-J9350
Topotecan Hydrochloride is a semi-synthetic derivative of camptothecin and is an anti-tumor drug with topoisomerase I-inhibitory activity. The cytotoxicity of topotecan is thought to be due to double strand DNA damage.

Hycamtin is FDA approved for treatment of metastatic carcinoma of the ovary and small cell carcinoma of the lung. Florida Medicare will cover Hycamtin for its FDA approved use, as well as for the treatment of the following off-labeled indications:

- Non-small cell carcinoma of the lung
- Myelodysplastic syndrome (MDS)
- Chronic myelomonocytic leukemia (CMML)

Trastuzumab (Herceptin®)-J9355
Trastuzumab is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. Trastuzumab’s’s targets are cancer cells that overexpress an oncogene called HER2 or HER2/neu, which occurs in high numbers in about 25 to 30 percent of breast cancers.

Herceptin is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have received one or more chemotherapy regimens for their metastatic disease.

Herceptin, in combination with paclitaxel, is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have not received chemotherapy for their metastatic disease.

Porfimer (Photofrin®)-J9600
Porfimer is a photosynthesizing agent that in combination with light, can cause cellular damage and tumor death. Tumor selectivity occurs as a result of selective distribution and retention of Porfimer on tumor tissue, and by selective delivery of light. Illumination of target tissue with 630 nanometer wavelength laser light induces a photochemical reaction that activates Porfimer.

Porfimer photodynamic therapy causes the release of thromboxane A2, which results in vasoconstriction, activation and aggregation of platelets, and increased clotting. These factors contribute to ischemic necrosis which leads to tissue and tumor death.

Porfimer is for intravenous use. It is supplied as a 75 mg single dose vial. After reconstitution, 2 mg per kg of body weight should be administered slowly over three to five minutes followed by illumination with laser light and debridement of the tumor at appropriate and specific intervals. Photodynamic treatment with Porfimer may be given for a total of three courses of therapy, each separated by at least 30 days.
Porfimer is FDA approved for the palliative treatment of partial or complete obstruction of the esophagus due to esophageal cancer in patients who cannot be satisfactorily treated with Nd:YAG laser therapy alone.

Porfimer is also FDA approved for patients with non-small cell lung cancer (NSCLC) for whom surgery and radiotherapy are not indicated.

**Denileukin diftitox (Ontak®)-J9999**

Denileukin diftitox is a fusion protein designed to direct the cytocidal action of diphtheria toxin to cells which express the IL-2 receptor.

Ontak is indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of the IL-2 receptor.

The safety and efficacy of Ontak inpatients with CTCL whose malignant cells do not express the CD25 component of the IL-2 receptor have not been examined.

**ICD-9-CM Codes that Support Medical Necessity**

To ensure reimbursement for this service, dual diagnoses must be submitted. The primary and secondary site of the malignancy must both be billed to indicate the breast malignancy is metastatic (e.g., ICD-9-CM code 174.0 and 198.5).

**J9045-Carboplatin (Paraplatin®, Paraplatin-AQ®)**

J9170-Docetaxel (Taxotere®)

140.0-149.9 172.0-172.9 183.0-183.9
151.0-151.9 174.0-174.9 185
161.0-161.9 175.0-175.9 188.0-188.9
162.2-162.9 176.0-176.9 195.0

J9181 & J9182-Etoposide (Etopophos®, Toposar®, VePesid®, VP-16)

151.0-151.9 176.0-176.9 200.00-200.88
155.0 182.0-182.8 201.00-201.98
155.2 183.0 202.00-202.98
160.0-160.9 183.9 203.00-203.01
162.2-162.9 186.0-186.9 204.00-204.01
164.0 188.0-188.9 205.00-205.01
170.0-170.9 189.0 205.10-205.11
171.0-171.9 190.5 206.00-206.01
173.0-173.9 191.0-191.9 207.00-207.01
174.0-174.9 194.0-194.9 236.1
175.0-175.9 199.0-199.1

J9185-Fludarabine (Fludara®)

200.00-200.88 204.10-204.11 206.00-206.01
202.00-202.98 205.00-205.01 207.00-207.01

J9201-Gemcitabine (Gemzar®)

157.0-157.9 175.0-175.9 188.0-188.9
162.2-162.9 183.0-183.9 189.0-189.2
174.0-174.9

J9206-Irinotecan (Camptosar®)

153.0-154.8 162.2-162.9 180.0-180.9

J9265-Paclitaxel (Taxol®)

140.0-149.9 175.0-175.9 185
150.0-150.9 176.0-176.9 188.0-188.9
151.0-151.9 180.0-180.9 195.0
161.0-161.9 182.0-182.8 197.2
162.2-162.9 183.0-183.9 199.0-199.1
174.0-174.9

J9280, J9290, & J9291-Mitomycin (Mutamycin®, mitomycin-C)

140.0-149.9 157.0-157.9 180.0-180.9
150.0-150.9 161.0-161.9 185
151.0-151.9 162.2-162.9 188.0-188.9
153.0-154.8 174.0-174.9 195.0
156.0-156.9 175.0-175.9 205.10-205.11

J9293-Mitoxantrone Hydrochloride (Novantrone®)

174.0-174.9 200.00-200.88 205.00-205.01
175.0-175.9 202.00-202.98 206.00-206.01
185 204.00-204.01 207.00-207.01

J9350-Topotecan Hydrochloride (Hycamtin®)

162.2-162.9 205.10 238.7
183.0-183.9 205.11

J9355-Trastuzumab (Herceptin®)

174.0-174.9 198.0 198.5
175.0-175.9 198.1 198.6
196.0-196.9 198.2 198.7
197.0-197.8 198.4 198.92

NOTE: The billing of Herceptin® requires dual diagnoses. To ensure reimbursement for this service, dual diagnoses must be submitted. The primary and secondary site of the malignancy must both be billed to indicate the breast malignancy is metastatic (e.g., ICD-9-CM code 174.0 and 198.5).
J9600-Porfimer (Photofrin®)
150.0-150.9 162.2-162.9

J9999-Denileukin diftitox (Ontak®)
202.10-202.18 202.20-202.28

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
When billing a chemotherapy drug that has a specific HCPCS code, use the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated.

When billing for Trastuzumab 10mg, use HCPCS code J9355 and include the name of the drug and the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated. The primary and secondary site of the malignancy must both be billed to indicate the breast malignancy is metastatic (e.g., ICD-9-CM code 174.0 and 198.5). Documentation which demonstrates that the patient’s tumor overexpresses the HER2 protein or gene must be maintained in the patient’s medical record.

When billing for Denileukin diftitox, use HCPCS code J9999 and include the name of the drug and the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated.

Documentation which demonstrates that the patient’s malignant cells express CD25 must be maintained in the patient’s medical record.

Documentation Requirements
Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician’s order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 12
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
2nd Qtr 2001 Update!
02/05/2001

Revised Effective Date:
Explanation of Revision:
Additional indications and ICD-9-CM codes were added to eight drugs.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Independent Diagnostic Testing Facilities (IDTFs)

The complete local medical review policy (LMRP) for IDTFs (policy number 00001) was published in the May/June 2000 Medicare B Update! (pages 22-38). The 2001 update to the Health Care Financing Administration’s Common Procedure Coding System (HCPCS) has necessitated the following updates to credentialling requirements, effective for services rendered on or after January 1, 2001:

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<td>CCI: RVS</td>
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Medical Policy Procedures: 12000
Policy Number
12000
Contractor Name
First Coast Service Options, Inc.
Contractor Number
00590
Contractor Type
Carrier
LMRP Title
Cosmetic/Reconstructive Surgery
AMA CPT Copyright Statement
CPT codes, descriptions, and other data only are copyright 1998 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Apply.
HCFA National Coverage Policy
Medicare Carriers Manual, Sections 2300, 2329
Coverage Issues Manual, Sections 35-12, 35-26, 35-40, 35-33
Primary Geographic Jurisdiction
Florida
Secondary Geographic Jurisdiction
N/A
HCFA Region
Region IV
HCFA Consortium
Southern
Policy Effective Date
01/01/1992
Revision Effective Date
01/01/2001
Revision Ending Effective Date
12/31/2000
Policy Ending Date
N/A
LMRP Description
Certain surgical procedures may be considered either cosmetic and/or reconstructive by descriptor. As a result, these surgical services must be reviewed for medical necessity.

Indications and Limitations of Coverage and/or Medical Necessity
When certain integumentary, musculoskeletal, respiratory, digestive system surgeries are performed, they must be reviewed for medical necessity since these surgeries may be cosmetic in nature. The list of surgeries are identified in the “CPT Codes” section of the policy.

The respiratory system surgery for excision or surgical planing of skin of nose for rhinophyma must be reviewed for medical necessity (procedure code 30120). Septoplasties (procedure codes 30520 and 30620) are covered services when performed for the reconstruction or to improve the function of the nasal airway.

The following medical indications for septoplasty must be reviewed for medical necessity:
- correction of congenital anomalies;
- correction of conditions resulting from accidental injuries;
- correction of deformities resulting from cancer surgery; and
- corrections of functional abnormalities (e.g., airway obstruction)

HCPCS Section & Benefit Category
Integumentary System/Surgery
Musculoskeletal System/Surgery
Respiratory System/Surgery
Digestive System/Surgery

CPT Codes
11920-11922
15780-15787
15788-15793
15831-15839
17106-17108
17360
17999
19316-19325
19328-19330
19340-19342
19350
19355
19357-19369
19370-19371
19380
19396
19499
21120-21123
21125-21127
21138-21139
21141-21180, 21188
21193-21199
21206
21208-21209
21210-21215
21230-21235
21240-21243
21244-21256
21260-21263
30120
30121
30520
30620
40840-40845
43842-43843
43846-43847
43850-43855
43860-43865
43999

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Surgical procedures performed to enhance the appearance of an individual are considered cosmetic and are not covered. These include but are not limited to the following:
Plastic surgery to correct moon face is not covered under the Medicare Program.

Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental and, therefore, is not covered.

Noncovered ICD-9-CM Code(s)  
N/A

Noncovered Diagnoses  
N/A

Coding Guidelines

Reconstruction of the affected breast and the contralateral unaffected breast (19340-19350, 19357-19369, 19380-19396, 19499) following a medically necessary mastectomy (19120-19240) are both considered relatively safe and effective noncosmetic procedures and are covered. The breast reconstruction surgery is covered following the removal of a breast for any medically related reason.

Documentation Requirements

Medical record documentation submitted with the claim must indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the history and physical and operative note. In addition to the history and physical and operative note, Attachment A or comparable information must be submitted when billing for gastric bypass surgeries (procedure codes 43842-43843, 43846-43847, 43850-43855, and 43860-43865). Also, when excessive skin is being excised (procedure codes 15831-15839), a pathology report is needed in addition to the history and physical and operative report.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

N/A

Advisory Committee Notes

N/A

Start Date of Comment Period  
N/A

Start Date of Notice Period  
02/01/2001

Revision History

Revision Number: 4  PCR B2001-003
Start Date of Comment Period:  N/A
Start Date of Notice Period:  02/01/2001  
2nd Qtr 2001 Update!

Revised Effective Date:  01/01/2001
Explanation of Revision:  Annual 2001 HCPCS Update

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

ATTACHMENT A

<table>
<thead>
<tr>
<th>Height (In Shoes)*</th>
<th>Weight in Pounds (In Indoor Clothing)†</th>
<th>Height (In Shoes)*</th>
<th>Weight in Pounds (In Indoor Clothing)†</th>
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<tr>
<td><strong>Men</strong></td>
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<td><strong>Women</strong></td>
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<tr>
<td>Ft.</td>
<td>In.</td>
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<td>Medium Frame</td>
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<tr>
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<tr>
<td>6</td>
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<td>155-168</td>
<td>164-178</td>
</tr>
</tbody>
</table>

1983 Metropolitan Height and Weight Tables for Men and Women  
According to Frame, Ages 25-59

*Shoes with 1-inch heels.
†Indoor clothing weighing 5 pounds for men and 3 pounds for women.

Source of basic data: Build Study, 1979, Society of Actuaries and Association of Life Insurance Medical Directors of America, 1980.  
Copyright 1983 Metropolitan Life Insurance Company.
Letter No. 415-416
Date of Service:    ________
Reference:   ____________

Dear Doctor:

Benefits for the treatment of “obesity” are provided by Medicare B only under limited conditions. To assist us in evaluating the above beneficiary’s claim, we require the following information for review:

1. Have the pressures of excess weight resulted in any physical trauma or disability?
   Yes ( ) No ( ) If yes, please describe in detail:

2. Are either pulmonary or circulatory insufficiencies present?________________________
   Have pulmonary function studies been done? If so, submit documented report.

3. Is arteriosclerosis, diabetes, coronary disease or endocrine disease present? If so, indicate current status and extent of condition(s). If condition(s) is under current treatment, please describe:

4. Have electrocardiograms or similar evaluations been performed? If so, submit copy of tracing and/or documented report.

5. Have any specific blood chemistries been done? If so, please submit documented report.

6. Is the patient able to function normally in his work and/or home environment?
   Comments:   __________________________________________________________

7. Patient’s Height ______, Weight ______, Age ______, Body Build (circle one): Small Frame ( ) Medium Frame ( ) Heavy Frame ( )

8. How long has present level of obesity been present?
   (years)

9. Has the patient attempted weight control through diet under the supervision of a physician? Yes ( ) No ( ). If yes, please indicate data and results obtained. (If another attending physician, please give name.)

10. If surgery has been (or is to be) performed in an attempt to relieve the obesity, please describe the indications for surgical intervention: ________________________________

11. General Comments: ________________________________

PREPARED BY: ________________________DATE: ________________________

Thank you for prompt attention to this matter.

Sincerely,

Special Claims
Medical Policy Procedures: 17304

Policy Number
17304

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Mohs' Micrographic Surgery (MMS)

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other date of publication of CPT). All Rights Reserved.

HCFA National Coverage Policy
Title XVIII of the Social Security Act, Section 1862 (a)
(7). This section excludes routine physical examinations.
Title XVIII of the Social Security Act, Section 1862 (a)
(1) (A). This section allows coverage and payment for
only those services that are considered to be medically
reasonable and necessary.

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
04/20/1998

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Mohs’ Micrographic Surgery (MMS) is the removal of
the tumor followed by marking of margins, immediate
frozen section histopathologic examination of margins
with subsequent reexcision of tumor-positive areas, and
final closure of the defect.

MMS is a precise tissue-sparing surgical technique used
in the removal and treatment of selected malignant
neoplasms of the skin. This surgery requires a single
surgeon to act in two distinct roles: surgeon and
pathologist.

MMS gives the highest cure rate for basal cell and
squamous cell skin lesions and results in the least amount
of tissue loss. This technique is generally employed for
high-risk tumors such as recurring tumors; large tumors;
lesions with poor differentiation histologically; lesions on
the ears, nose, lip; and neurotropic lesions.

The majority of simple skin cancers can be managed
by simple excision or destruction techniques. The
medical records should clearly show that Mohs’
surgery was chosen because of the complexity or size
or location of the lesion.

MMS is usually an office procedure done under local
anesthesia and/or sedation.

Indications and Limitations of Coverage and/
or Medical Necessity

Florida Medicare will consider reimbursement for Mohs’
Micrographic Surgery for accepted diagnoses and
indications. The current accepted diagnoses and indications
are listed in this policy. The physician performing the
Mohs’ Micrographic Surgery must be trained and highly
skilled in MMS technique and pathology identification. The
physician must document in the patient’s medical record
that the diagnosis is appropriate for MMS and that MMS is
the most appropriate choice for the treatment of the
particular lesion.

Current accepted diagnoses and indications for Mohs’
Micrographic Surgery are:

- Basal Cell Carcinomas, Squamous Cell Carcinomas, or
  Basalosquamous Cell Carcinomas in anatomic
  locations where they are prone to recur:
  - Central facial areas, nose, and temple areas of
    the face (the so-called “mask area” of the face)
    which includes the eyebrows and periobital
    areas, the superolateral temple areas, and the
    preauricular and postauricular areas;
  - Lips, cutaneouse and vermillion;
  - Eyelids;
  - The entire external ear and ear canal; and
  - Auricular helix and canal.

- Other Skin Lesions:
  1. Angiosarcoma of the skin
  2. Keratoacanthoma, recurrent
  3. Dermatofibrosarcoma protuberans
  4. Malignant fibrous histiocytoma
  5. Sebaceous gland carcinoma
  6. Microsystic adnexal carcinoma
  7. Extramammary Paget’s Disease
  8. Bowenoid papulosis
  9. Merkel cell carcinoma
  10. Bowen’s disease (squamous cell carcinoma in situ)
  11. Adenoid type of squamous cell carcinoma
  12. Rapid growth in a squamous cell carcinoma
  13. Longstanding duration of a squamous cell
      carcinoma
  14. Verrucous carcinoma
  15. Atypical Fibroxanthoma
  16. Leiomyosarcoma or other spindle cell neoplasms
      of the skin
  17. Adenocystic carcinoma of the skin
  18. Erythroplasia of Queyrat
  19. Oral and central facial, paranasal sinus neoplasm
  20. Apocrine carcinoma of the skin
  21. Malignant melanoma or melanoma-in-situ
      (facial, auricular, genital and digital) when
      anatomical or technique difficulties do not allow
      conventional excision with appropriate margins
22. Rare, biopsy-proven skin malignancies not otherwise addressed in the section; and
23. Basal cell carcinomas, squamous cell carcinomas, or basaloquamous carcinomas that have one or more of the following features:
   - Recurrent
   - Biopsy proven lesions with aggressive pathology as documented by at least one of the following microscopic characteristics:
     - sclerotic
     - fibrosing
     - morphealike
     - metatypical/infiltrative/spikey shaped cell groups
     - perineural or perivascular invasion
     - nuclear pleomorphism
     - high mitotic activity
     - superficial multicentri
   - located in the following areas:
     - genitalia
     - digits
     - nail unit/periungual
   - Large size (1.0 cm or greater in the non-mask areas of the face and 2.0 cm or greater in other areas)
   - Positive margins on recent excision
   - Poorly defined borders
   - In the very young (< 40 yr. age)
   - Radiation-induced
   - In patients with proven difficulty with skin cancers or who are immunocompromised
   - Basal Cell Nevus Syndrome
   - In an old scar (e.g., a Marjolin’s ulcer)
   - Associated with xeroderma pigmentosum
   - Perineural invasion on biopsy
   - Difficulty estimating depth of lesion

• Laryngeal Carcinoma

Medicare will closely monitor the appropriate billing of the MMS procedure codes through its normal medical review activities. Failure to properly document may result in the denial of claims(s).

HCPCS Section & Benefit Category
Integumentary System/Surgery

CPT Codes
17304  17305  17306
17307  17310

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
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<tr>
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<td>173.3</td>
</tr>
<tr>
<td>173.0</td>
<td>173.8*</td>
</tr>
</tbody>
</table>

* If Mohs’ Micrographic Surgery is being submitted for one of the skin diagnoses listed under “Other Skin Lesions,” the claim must be submitted with diagnosis code 173.8 (malignant neoplasm, other specified site(s) of skin). Documentation, referencing the number of designation of the appropriate lesion in the “Other Skin Lesions” category list and supporting medical necessity of the procedure must be available if requested by Medicare.

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
Claims will be denied when Medicare determines that the services were not medically reasonable and necessary, or that services were determined to fall under one of the Medicare “Exclusions”, e.g., cosmetic surgery.

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
No payment will be allowed for the biopsy and pathology of a lesion on the day of Mohs’ surgery. An exception would be if the surgeon was unable to obtain the biopsy report with reasonable efforts. The medical record should clearly demonstrate that the surgeon was unable to obtain the biopsy report with reasonable efforts.

Medicare is aware that a biopsy is necessary in order for the physician to determine the exact nature of the lesion(s) to be removed. Occasionally, that biopsy may need to be done on the same day that the Mohs’ surgery is performed. In order to allow separate payment for a biopsy and pathology on the same day as MMS, the -59 modifier is appropriate. The -59 modifier is only to be used when there has not been a biopsy of the lesion for which Mohs’ surgery is performed, within 60 days of the Mohs’ surgery or when the Mohs’ surgeon cannot obtain a pathology report, with reasonable effort, from the referring physician or when the biopsy is performed on a lesion that is not associated with the Mohs’ surgery.

Report the -59 modifier on the same detail line as the biopsy procedure code and one of the pathology procedure codes: 88304, 88305, 88307, 88331, or 88332. Do not report the -59 modifier on the same detail line as the Mohs’ surgical procedure.

Some tumors may require more than three Mohs’ micrographic surgical stages for complete removal of tumor. The appropriate code to submit for each additional stage is 17307.

If more than 5 specimens are obtained during any stage, then procedure code 17310 should be billed for each additional specimen in addition to the appropriate stage code.
Diagnosis(es) must be present on any claim submitted, and must be coded to the highest level of specificity.

Documentation Requirements
The surgeon’s documentation in the patient’s medical record should be legible and support the medical necessity of this procedure. The operative notes and pathology documentation in the patient’s medical record should clearly show that Mohs’ micrographic surgery was performed using accepted Mohs’ technique, in which the physician acts in two integrated and distinct capacities: surgeon and pathologist (i.e., the medical records should demonstrate that true Mohs’ surgery was performed). In addition, there should be a pathologic description of slides described in the medical record and all slides should be retained.

If the -59 modifier was used with a skin biopsy/pathology code on the same day the Mohs’ surgery was performed, the physician’s documentation should clearly indicate that:

- the biopsy was performed on a lesion other than the lesion that the Mohs’ surgery was performed upon; or
- if the biopsy is of the same lesion that the Mohs’ surgery was performed upon, a biopsy of that lesion had not been done within the previous 60 days; or
- if a recent (within 60 days) biopsy of the same lesion that Mohs’ surgery was performed on had been done, the results of that biopsy were unobtainable by the Mohs’ surgeon using reasonable effort.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Society of Dermatology.

Start Date of Comment Period
N/A

Start Date of Notice Period
12/15/2000

Revision History
Revision Number: 1 PCR B2001-004
Start Date of Comment Period: N/A
Start Date of Notice Period: 12/15/2000
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 20974

Policy Number
20974

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Osteogenic Stimulation

AMA CPT Copyright Statement
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HCFA National Coverage Policy
Coverage Issues Manual, Section 35-48

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
1994

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Electrical stimulation to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.
Indications and Limitations of Coverage and/or Medical Necessity

Noninvasive Stimulator (procedure code 20974):
The noninvasive stimulator device is covered only for the following indications:
- Nonunion of long bone fractures;
- Failed fusion, where a minimum of nine months has elapsed since the last surgery;
- Congenital pseudarthroses; and
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Invasive (Implantable) Stimulator (procedure code 20975):
The invasive stimulator device is covered only for the following indications:
- Nonunion of long bone fractures; and
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Effective for services performed on or after September 15, 1980, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after six or more months have elapsed without healing of the fracture.

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Ultrasonic Osteogenic Stimulators (procedure code 20979)
An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound using conductive gel in order to stimulate fracture healing.

Effective for services performed on or after January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures. In demonstrating nonunion of fractures, we would expect:
- A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph must include views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.
- Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Non-unions of the skull, vertebrae, and those that are tumor-related are excluded from coverage. The ultrasonic stimulator may not be used concurrently with other non-invasive osteogenic devices. The national non-coverage policy related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain in place.

HCPCS Section & Benefit Category
Musculoskeletal System/Surgery

CPT Codes
20974
20975
20979

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
For procedure code 20974, the following ICD-9-CM codes apply (not an all inclusive list)
733.81
733.82
996.4
V45.4

For procedure code 20975, the following ICD-9-CM codes apply (not an all inclusive list):
733.81
733.82

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Ultrasonic osteogenic stimulators used for non-union of the skull, vertebrae, and those that are tumor-related are excluded from coverage. In addition, national non-coverage related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain in place.

Noncovered ICD-9-CM Codes
N/A

Noncovered Diagnoses
N/A

Coding Guidelines
Bill the CPT code which describes the services rendered and the ICD-9-CM code which describes the medical condition being treated.

When billing for the Osteogenesis Stimulator, electrical, (surgically implanted), the procedure should be coded as E0749.
Documentation Requirements
Documentation must support that this service meets the requirements as listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the policy. This information is normally found in the office/progress notes and/or operative report.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
N/A

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Orthopedic and Surgical Societies.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 5
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
2nd Qtr 2001 Update!
Revision Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update with incorporation of coverage criteria for ultrasonic osteogenic stimulators based on change request 1383 (transmittal 131 dated Nov 2000)

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 22520
Policy Number
22520

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Percutaneous Vertebroplasty

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HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
04/17/2000

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Percutaneous vertebroplasty is a therapeutic, interventional neurosurgical and radiological procedure that consists of the percutaneous injection of a biomaterial, methyl methacrylate, into a lesion of a cervical, thoracic, or lumbar vertebral body. The procedure is utilized for pain relief and bone strengthening of weakened vertebral bodies.

The procedure is performed under fluoroscopic guidance, although some prefer the use of computed tomography (CT) with fluoroscopy for needle positioning and injection assessment. An intraosseous venogram is sometimes performed before cement injection to determine whether the needle is positioned within a direct venous anastomosis to the central or epidural veins, to minimize extravasation into venous structures. General anesthesia or neuroleptanalgesia with additional local anesthesia (1% lidocaine) is utilized, as pain may intensify during cement injection. The methyl methacrylate is injected into the vertebral body until resistance is met or until cement reaches the posterior wall. The procedure usually lasts from 1 to 2 hours, unless cement is injected into two or more vertebral bodies. The patient must remain flat for about three hours following the procedure.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider the performance of a percutaneous vertebroplasty procedure medically reasonable and necessary for the following indications:

- Painful osteolytic vertebral metastasis;
- Painful myeloma;
- Painful and/or aggressive hemangioma; and
- Painful, debilitating, osteoporotic vertebral collapse/compression fractures that have not responded to appropriate medical treatment (e.g., 2-4 week period of immobilization such as restricted activity/bracing and analgesia/scheduled narcotic).
The decision to perform this procedure should be multidisciplinary, taking into consideration the following factors: the local and general extent of the disease, the spinal level involved, the severity of pain experienced by the patient, previous treatments and their outcomes, as well as the patient’s neurological condition, general state of health and life expectancy.

Percutaneous vertebroplasty is contraindicated in coagulation disorders due to the large diameter of the needles used for injection.

Relative contraindications to performance of a percutaneous vertebroplasty are extensive vertebral destruction, significant vertebral collapse (i.e., vertebra reduced to less than one-third its original height), neurological symptoms related to compression, and when there is no neurosurgical backup for emergency decompression in the event a neurological deficit develops during the injection of methyl methacrylate.

HCPCS Section & Benefit Category
Surgery/Musculoskeletal System
Radiology/Diagnostic Radiology

CPT Codes
22520
22521
22522
76012
76013

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
170.2
198.5
203.00-203.01
228.09
238.6
733.13
805.00-805.9

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
CPT code 22520 and/or 22521 should only be billed one time, regardless of the number of injections to the one vertebral body.

If more than one vertebra is injected, CPT code 22522 may be billed in accordance with the multiple surgery billing guidelines.

Documentation Requirements
Medical record documentation (e.g., office/progress notes, procedure notes) maintained by the provider must indicate the medical necessity for performing this service. The documentation must also support that the service was performed.

When the service is performed for painful, debilitating, osteoporotic vertebral collapse/compression fractures, documentation must support that conservative treatment has failed.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Radiological Society, Inc.

Carrier Advisory Committee meeting held on November 13, 1999.
Transmyocardial Revascularization

The high-powered carbon dioxide (CO₂) laser delivers approximately 40 joules of energy with each burst. The burst is timed to coincide with the beginning of ventricular systole. At this point, the ventricles are full of blood, all valves are closed, and intraventricular pressure is high. When the laser beam passes through the heart wall into the ventricular chamber, the blood in the cavity absorbs the remaining energy. This prevents the beam from passing through the other side of the heart and entering tissues. In addition, penetrating the myocardium at this point in the cardiac cycle also reduces the likelihood of ventricular arrhythmias.

The holmium: YAG laser delivers short bursts of low energy into the myocardium. Because the energy does not penetrate beyond the myocardial tissue that is in direct contact with the laser, there is no need to have blood in the ventricular chamber to act as a backstop for the beam.

To determine when the laser beam has penetrated the myocardium, the physician uses transesophageal echocardiography. A burst of bubbles in the left ventricle appears on the screen when the laser beam has penetrated the myocardium.

The surgeon stops the bleeding from each newly-created channel by applying pressure to the site with his fingers until the blood clots.

Since TMR is performed on the beating heart, a cardiopulmonary machine is not utilized during the procedure. Consequently, the risk of decreased cardiac output, extravascular volume changes, renal and central nervous system alterations, and other complications normally associated with bypass is minimized.

TMR does not provide increased life expectancy, nor is it proven to affect the underlying cause of angina. However, it appears effective in treating the symptoms of angina, reducing hospitalizations, and allowing patients to resume some of their normal activities of daily living.

Indications and Limitations of Coverage and/or Medical Necessity

Medicare will consider TMR medically reasonable and necessary when performed for dates of service on or after July 1, 1999 as a last resort for patients with severe angina (stable or unstable) that meet all of the following criteria:

- Class III or Class IV angina based on the Canadian Cardiovascular Society Classification scale or an equivalent classification scale. Patients in Class III experience a marked limitation of ordinary physical activity, whereas those in Class IV are unable to carry out any physical activity without discomfort.
- The patient has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages.
- The angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty (PTCA), stenting, coronary atherectomy, or coronary bypass.
• Have an ejection fraction of 25% or greater.
• Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention.
• Have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Coverage is further limited to those uses of the laser (used in performing the procedure) which have been approved by the Food and Drug Administration for the purpose for which they are being used.

In addition, the following coverage requirements apply:
• The physician must be properly trained in this procedure.
• The provider of this service must document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, are trained in the procedure and the proper use of the equipment involved.
• The facility must have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy.
• The providers must conform to the standards for laser safety set by the American National Standards Institute, ANSIZ1363.

HCPCS Section & Benefit Category
Cardiovascular System/Surgery

CPT Codes
33140
33141

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
411.1
413.9

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
Procedure code 33140 should be billed when TMR is performed as a distinct separate procedure (i.e., thoracotomy performed for the sole purpose of TMR). When TMR is performed as an add-on to thoracotomies performed for other reasons (e.g., CABGs), procedure code 33141 should be billed.

Documentation Requirements
The medical record documentation must support that the patient meets all of the criteria contained in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy. In addition, the documentation must support that the service was performed. This information is usually found in the history and physical, progress note, operative note, diagnostic test results, and/or discharge summary.

Documentation verifying the laser’s FDA approval, appropriate training of the physician and all ancillary personnel, facility requirements, and that the laser safety standards are being followed must be available at the facility.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from Florida Chapter of the American College of Cardiology.

Carrier Advisory Committee meeting held on 8/21/1999.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 3 PCR B2001-008
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
Revised Effective Date: 01/01/2001
2nd Qtr 2001 Update!
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Medical Policy Procedures: 33216

Policy Number
33216

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Implantation of Automatic Defibrillators

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HCFA National Coverage Policy
Coverage Issues Manual, Section 35-85

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
1994

Revision Effective Date
11/27/2000

Revision Ending Effective Date
11/26/2000

Policy Ending Date
N/A

LMRP Description
The implantable automatic defibrillator is an electronic device designed to detect and treat life threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.

Indications and Limitations of Coverage and/or Medical Necessity
Effective for services performed on or after January 24, 1986 through July 1, 1991, the implantation of an automatic defibrillator is a covered service only when used as a treatment of last resort for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. Patients must also be found, by electrophysiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy). It must be emphasized that unless all of the above-described conditions and stipulations are met in a particular case, including the inducibility of tachyarrhythmia, etc., implantation of an automatic defibrillator may not be covered.

Effective for services performed on or after July 1, 1991, the implantation of an automatic defibrillator is a covered service for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction.

Effective for services performed on or after July 1, 1999, the implantation of an automatic defibrillator is also a covered service for patients with the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or,
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

In addition to the above indications, removal and replacement of an automatic defibrillator is a covered service in such cases as mechanical complications and/or the end of the functional capacity of the device.

HCPCS Section & Benefit Category
Cardiovascular System/Surgery

CPT Codes
33216
33217
33218
33220
33223
33240
33241
33243
33244
33245
33246
33249

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
425.1
427.5
996.04
425.4
794.31
V53.32
427.1

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A
**Coding Guidelines**
N/A

**Documentation Requirements**
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the services being billed. In addition, documentation that the service was performed must be included in the patient's medical record. This information is normally found in the office/progress notes, hospital notes, and/or operative report.

**Utilization Guidelines**
N/A

**Other Comments**
N/A

**Sources of Information**
N/A

**Advisory Committee Notes**
N/A

### Medical Policy Procedures: 36521

**Policy Number**
36521

**Contractor Name**
First Coast Service Options, Inc.

**Contractor Number**
00590

**Contractor Type**
Carrier

**LMRP Title**
Protein A Column Apheresis

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**HCFA National Coverage Policy**
Coverage Issues Manual, Section 35-90
Medicare Carriers Manual, Sections 4421.1-4137

**Primary Geographic Jurisdiction**
Florida

**Secondary Geographic Jurisdiction**
N/A

**HCFA Region**
Region IV

**HCFA Consortium**
Southern

**Policy Effective Date**
05/05/1991

**Revision Effective Date**
01/01/2001

**Revision Ending Effective Date**
12/31/2000

**Policy Ending Date**
N/A

**Revision History**

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2nd Qtr 2001 Update!

**Explanation of Revision:**
Revision was needed to add an indication and applicable diagnoses to address removal and replacement of AICDs due to functional ineffectiveness and mechanical complications.

**Advance Notice Statement**
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

**LMRP Description**
Protein A columns are plasma treatment devices that contain highly-purified staphylococcal A protein bound to an inert silica matrix. The technique involves pumping the patient’s blood through a cell separator and perfusing the collected plasma over the adsorbent column. The mechanism of action is presumed to be an immunoadsorption of circulating immune complexes and platelet-specific autoantibodies. Extracorporeal Immunoadsorption (ECI), using protein A columns, has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases.

**Indications and Limitations of Coverage and/or Medical Necessity**
Protein A column apheresis will be covered by Florida Medicare when used for the treatment of refractory Idiopathic Thrombocytopenia Purpura (ITP) and, effective for services rendered on or after January 1, 2001 only, Rheumatoid Arthritis (RA) will also be covered.

Refactory ITP is defined, for the purposes of this policy, as meeting the following criteria:
- Failure of prior treatments such as corticosteroids and/or splenectomy
- No concurrent illness/disease explaining thrombocytopenia
- Platelet counts persistently at or below 25,000/cu mm

RA is defined, for the purposes of this policy, as meeting the following criteria:
- Disease must be severe
- Disease must be active as evidenced by having:
  - Greater than 5 swollen joints,
  - Greater than 20 tender joints, and
  - Morning stiffness greater than 60 minutes.
- Patients must have failed an adequate course of a minimum of three (3) Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.
HCPCS Section & Benefit Category
Surgery/Cardiovascular System

CPT Codes
36521

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
287.3
714.0
714.1
714.2
714.30-714.33

NOTE: the ICD-9-CM codes shown above in italics are effective for services rendered on or after January 1, 2001 only

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Documentation Requirements
Medical record documentation that is maintained by the performing physician must substantiate the medical necessity for the use of Protein A Column Apheresis by clearly indicating the relevant clinical signs and symptoms related to the condition for which this therapy is indicated. This documentation is usually found in the history and physical or in the office/progress notes.

The medical record must clearly reflect the failure of conservative therapies for refractory ITP and rheumatoid arthritis as defined under “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy. The medical record must also identify the failed DMARDS.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives numerous societies.

Carrier Advisory Committee Meeting held on 2/19/2000.

Start Date of Comment Period
02/11/2000

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 2  PCR B2001- 058
Start Date of Comment Period: 02/11/2000
Start Date of Notice Period: 02/01/2001
2nd Qtr 2001 Update!
Revised Effective Date: 01/01/2001
Explanation of Revision: A statement regarding coverage of rheumatoid arthritis and additional ICD-9-CM codes were added to policy.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
12/18/1995

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Colonoscopy allows direct visual examination of the intestinal tract with a flexible tube containing light transmitting glass fibers that return a magnified image. Colonoscopy can act as both a diagnostic and therapeutic tool in the same procedure. Therapeutic indications include removal of polyps or foreign bodies, hemostasis by coagulation, and removal of tumors.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider a colonoscopy to be medically necessary under any of the following circumstances (see Covered ICD-9-CM Codes):

- Evaluation of an abnormality on barium enema which is likely to be clinically significant, such as a filling defect or stricture.
- Evaluation and excision of polyps detected by barium enema or flexible sigmoidoscopy.
- Evaluation of unexplained gastrointestinal bleeding; hematochezia not thought to be from rectum or perianal source, melena of unknown origin, or presence of fecal occult blood.
- Unexplained iron deficiency anemia.
- Examination to evaluate the entire colon for simultaneous cancer or neoplastic polyps in a patient with a treatable cancer or neoplastic poly.
- Evaluation of a patient with carcinoma of the colon before bowel resection. Post surgical follow-up should be conducted annually for 2 years and every 2 years thereafter.
- Yearly evaluation with multiple biopsies for detection of cancer and dysplasia for patients with chronic ulcerative colitis who have had pancolitis of greater than seven years duration.
- Yearly evaluation with multiple biopsies for detection of cancer and dysplasia for patients with chronic ulcerative colitis who have had left-sided colitis of over 15 years duration (not indicated for disease limited to rectosigmoid).
- Chronic inflammatory bowel disease of the colon when more precise diagnosis or determination of the extent of activity of disease will influence immediate management.
- Clinically significant diarrhea of unexplained origin.
- Treatment of bleeding from such lesions as vascular anomalies, ulceration, neoplasia, and polyectomy site (e.g., electrocoagulation, heater probe, laser or injection therapy).
- Foreign body removal.
- Decompression of acute non-toxic megacolon.
- Balloon dilation of stenotic lesions (e.g., anastomotic strictures).
- Decompression of colonic volvulus.
- Examination and evaluation when a change in management is probable or is being suspected based on results of the colonoscopy.
- Evaluation within 6 months of the removal of sessile polyps to determine and document total excision. If evaluation indicates that residual polyp is present, excision should be done with repeat colonoscopy within 6 months. After evidence of total excision without return of the polyp, repeat colonoscopy yearly.
- If a total colonoscopy is unsuccessful preoperatively due to obstructive cancer, repeat colonoscopy 3-6 months post-operatively unless unresectable metastases are found at surgery.
- Evaluation to differentiate between ulcerative and Crohn’s colitis.
- Evaluation 3 years after resection of newly diagnosed small (<5mm diameter) adenomatous polyps when only a single polyp was detected. After 1 negative 3-year follow-up examination subsequent surveillance intervals may be increased to 5 years.
- Evaluation at 1 and 4 year intervals after resection of multiple or large (≥10mm) adenomas. Subsequent surveillance intervals may then be increased to every 5 years.
- Evaluation of low to high grade dysplasia in flat mucosa by colonoscopy 6 months after undergoing aggressive medical therapy, especially when inflammatory changes were present.
- Evaluation in 1 year after the removal of multiple adenomas. If examination proves negative then repeat in 3 years. After 1 negative 3-year follow-up examination, repeat exam every 5 years.
- Evaluation of a patient presenting with signs/symptoms (e.g., rectal bleeding, abdominal pain) of a disorder that appears to be related to the colon.

HCPCS Section & Benefit Category
Surgery/Digestive System

CPT Codes
44388  44393  45378  45383
44389  44394  45379  45384
44390  44397  45380  45385
44391  45355  45382  45387
44392

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
009.0-009.1  198.89  235.5  560.81-560.89
009.3  199.0  239.0  560.9
038.9  199.1  280.0  562.11
152.2  201.90  280.9  562.12
153.0-153.9  211.2  281.9  562.13
154.0-154.8  211.3  448.0  564.0
155.2  211.4  555.0-555.9  564.1
176.3  211.8  556.0-556.9  564.4
195.2  230.3  557.0-557.9  564.5
197.0  230.4  558.1-558.9  564.7
197.5  230.5  560.0  564.81-564.89
197.6  230.6  560.1  569.0
197.7  230.9  560.2  569.3
198.3  235.2  560.30-560.39  569.41
Prior to 1/1/97
A failed colonoscopy, e.g., the inability to extend beyond the splenic flexure, should be billed and paid as a sigmoidoscopy, (CPT code 45330) rather than a colonoscopy, since this is the procedure that was actually performed. Procedure code modifier 22 should be used and extra payment allowed only when supporting documentation indicates that significantly more time and effort is involved than is required in the typical sigmoidoscopy. The fact that a particular sigmoidoscopy was intended to be a colonoscopy does not in itself automatically justify the use of modifier 22. (PQAB:KB, May 18, 1995)

Effective 1/1/97
Incomplete colonoscopies should be billed as procedure code 45378-53 beginning with services provided on or after January 1, 1997. Procedure code 45378-53 is included in the 1997 Medicare Physician Fee Schedule Database (MPFSDB). The relative value units (RVU) will be the same as procedure code 45330 (sigmoidoscopy). There will be no site-of-service reduction. Providers will be able to file claims for failed colonoscopies electronically. (11/4/96-Prof 015B)

For screening colonoscopies, refer to Florida Medicare’s Local Medical Review Policy G0104 (Colorectal Cancer Screening).

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Documentation Requirements
Medical record documentation (office/progress notes) maintained by the ordering/referring physician must indicate the medical necessity of the colonoscopy procedure covered by the Medicare program. The procedure results/report and any associated pathology report must be included in the patient’s medical record.

If the provider of the colonoscopy is other than the ordering/referring physician, the provider of the service must maintain hard copy documentation of procedure results/report and pathology report along with copies of the ordering/referring physician’s order for the procedure.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Gastroenterology Society.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 7  
Start Date of Comment Period: N/A  
Start Date of Notice Period: 02/01/2001  
Revised Effective Date: 01/01/2001  
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

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HCFA National Coverage Policy
Coverage Issues Manual, Section 35-96

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A
HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/01/1999

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland.

CSAP can be carried out under general or spinal anesthesia and lasts approximately 2-3 hours. Five to six cryoprobes are placed transperinally under transrectal ultrasound (TRUS). Once the probes are in place, freezing is carried out while observing under TRUS the increasing echoes as the block of frozen prostate tissue approaches the rectal mucosa. Such monitoring minimizes the risk of rectal freezing. The possibility of injury to the urethra is decreased by the use of a warming device which is inserted into the urethra.

Indications and Limitations of Coverage and/or Medical Necessity
Effective for services performed on or after July 1, 1999, Medicare will consider cryosurgery of the prostate medically reasonable and necessary under the following circumstance:
• For primary treatment of patients with clinically localized, stages T1-T3, prostate cancer.

The evidence is not yet sufficient to demonstrate the effectiveness of this procedure as salvage therapy for local failures after radical prostatectomy, external beam irradiation, and brachytherapy. Therefore, cryosurgery of the prostate as salvage therapy is not covered under Medicare.

HCPCS Section & Benefit Category
Male Genital System/Surgery

CPT Codes
55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Documentation Requirements
Medical record documentation maintained in the patient’s file must demonstrate that the service was performed as a primary treatment for clinically localized stage T1-T3 prostate cancer. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or operative report.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
N/A

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 1 PCR B2001-011
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Medical Policy Procedures: 62263
Policy Number
62263
Contractor Name
First Coast Service Options, Inc.
Contractor Number
00590
Contractor Type
Carrier
LMRP Title
Percutaneous Lysis of Epidural Adhesions
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HCFA National Coverage Policy
N/A
Primary Geographic Jurisdiction
Florida
Secondary Geographic Jurisdiction
N/A
HCFA Region
Region IV
HCFA Consortium
Southern
Policy Effective Date
03/19/2001
Revision Effective Date
N/A
Revision Ending Effective Date
N/A
Policy Ending Date
N/A
LMRP Description
Percutaneous epidural lysis of adhesions (also referred to as epidural neuroplasty or epidural adhesiolysis) is an interventional pain management technique that is used to treat chronic low back pain with radiculopathy. The basis for performing this procedure is the premise that fibrous adhesions (scar tissue) develops after surgery, trauma, and/or inflammation that compounds pain associated with the nerve root by fixing it in one position and thus increasing the susceptibility of the nerve root to tension or compression. This scar tissue also prevents the direct application of medications to relieve pain (local anesthetics and corticosteroids) to the problem area. The goal of the procedure is to break down these fibrous adhesions to allow for delivery of high concentrations of injected drugs to the target area and free the nerve from mechanical tension/compression. The procedure usually involves either endoscopic or non-endoscopic (under fluoroscopy) placement of an epidural catheter and sequential adhesiolysis procedures performed over a 1-3 day period. Adhesiolysis can be accomplished by solution injection (commonly hypertonic saline and/or hyaluronidase) and/or by mechanical means (by maneuvering a specially designed epidural catheter or epiduroscope).

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider the use of percutaneous lysis of epidural adhesions to be medically reasonable and necessary in the treatment of chronic refractory low back pain with radiculopathy that has failed to respond to more conservative treatment measures. This more conservative treatment may include local heat, traction, nonsteroidal anti-inflammatory medications, and anesthetic and/or steroid epidural injections. The chronic refractory low back pain may be secondary to post lumbar laminectomy syndrome, intervertebral lumbar disc disruption, lumbar epidural adhesions, and/or lumbar degenerative disc disorder.

HCPCS Section & Benefit Category
Nervous System/Surgery
CPT Codes
62263 Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, spring-wound catheter) including radiologic localization (includes contrast when administered)

Not Otherwise Classified Codes (NOC)
N/A
ICD-9-CM Codes that Support Medical Necessity
722.10 722.73 724.4
722.52 722.83
Diagnoses that Support Medical Necessity
N/A
ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A
Diagnoses that DO NOT Support Medical Necessity
N/A
Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.
Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.
Noncovered Diagnoses
N/A
Percutaneous lysis of epidural adhesions involves the placement of an epidural catheter that may remain in place over several days for the purpose of lysis of adhesions. Procedure code 62263 is not reported for each adhesiolysis treatment, but should be reported once to describe the entire series of injections/infusions regardless of how many days or how many specific areas of scarring and inflammation in the epidural space are treated.

Procedure code 62263 includes the injection of contrast material for epidurography and subsequent fluoroscopic guidance and localization performed in association with sequential adhesiolysis treatment(s). Therefore, it would not be appropriate to report procedure codes 72275 (Epidurography, radiological supervision and interpretation) or 76005 [Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural, transfemorar epidural, subarchnoid, paravertebral facet joint, paravertebral facet joint nerve or sacroiliac joint), including neurolytic agent destruction] in addition to procedure code 62263. Procedure code 72275 can be reported in addition to procedure code 62263 only if all components of that procedure code (a formally interpreted contrast study involving multiplanar imaging generating “hard copy” images) are met.

Procedure code 62263 may be performed with an epiduroscope as a technical procedural option rather than using fluoroscopy to direct catheter placement for either mechanical or solution lysis of adhesions. If an epiduroscope is used as a technical procedural option, it would not be appropriate to bill the unlisted nervous system procedure code 64999 (there is no procedure code to represent epiduroscopy) in addition to reporting procedure code 62263. Furthermore, Florida Medicare has identified epiduroscopy/myeloscopy performed as a separate procedure as a noncovered service as identified in Florida Medicare’s “List of Medicare Noncovered Services.”

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

In addition, the medical record should clearly document the nature of the chronic refractory low back pain. This should include the location, intensity, type of pain present, and contributing factors (if any), duration of condition, and treatment regimes that have been utilized. Documentation should demonstrate failure of more conservative management in the treatment of the patient’s condition. This more conservative treatment may include local heat, traction, nonsteroidal anti-inflammatory medications, and anesthetic and/or steroid epidural injections.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Society of Anesthesiologists, Florida Society of Physical Medicine and Rehabilitation, and the Florida Neurosurgical Society.

Carrier Advisory Committee Meeting held on November 11, 2000.

Start Date of Comment Period
11/03/2000

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: Original PCR B2001-066
Start Date of Comment Period: 11/03/2000
Start Date of Notice Period: 02/01/2001

Original Effective Date: 03/19/2001

2nd Qtr 2001 Update!

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Epidural/Subarachnoid Injections for Diagnostic Purposes

Florida Medicare will consider the use of epidural/subarachnoid injections for diagnostic purposes to be medically reasonable and necessary in the following circumstances:

- Chronic pain syndromes (generally lasting more than six months) including chronic cervical, thoracic, and lumbar pain with radiculopathy, spinal stenosis, phantom limb pain, reflex sympathetic dystrophy, complex regional pain syndrome, and vertebral compression fractures.
- Chronic pain due to intervertebral disc disease with neuritis, radiculitis, or myelopathy.
- Intractable post herpetic neuralgia.
- Chronic severe pain due to carcinoma.
- Post-laminectomy syndrome (failed back syndrome).
- Post-traumatic neuropathy of the spinal nerve roots.
- Acute/subacute pain syndromes including cervical, thoracic, and lumbar pain with radiculopathy and intervertebral disc disease with neuritis, radiculitis, or myelopathy that has failed to respond to adequate conservative management. (Subacute conditions would refer to recurrent and/or exacerbation of an acute condition).

Diagnostic and/or therapeutic injections are considered to be medically necessary for the management of acute, subacute or chronic pain syndromes that have failed to respond to conservative management. However, it is prudent medical practice to evaluate the patient thoroughly and to provide the modality most likely to establish or treat the presumptive diagnosis. If the first procedure fails to produce the desired effect and rules out that possibility, then it would be appropriate to proceed to the next logical treatment. Therefore, it would generally not be expected to see epidural injections, sympathetic nerve blocks, multiple facet joint injections, and paravertebral nerve blocks in any and all combinations to be administered to the same patient on the same day. Such therapy can lead to an improper diagnosis or unnecessary treatment. Furthermore if the patient has no positive response to the first epidural injection, repeat injection’s would not be considered medically reasonable and necessary.

Epidural/Subarachnoid Injections for Acute Post-Operative Pain Control

Florida Medicare will consider the use of epidural/subarachnoid injections for post-operative pain management in the following circumstances:

- When the surgeon and/or anesthesiologist determines post-operative pain is sufficient to require this level of pain management.
- For those procedures for which the surgeon and/or anesthesiologist feels it is reasonable to expect that post-operative pain will be sufficient to require this level of pain management.

HCPCS Section & Benefit Category
Nervous System/Surgery
CPT Codes
62310  62318
62311  62319

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>CPT Code 1</th>
<th>CPT Code 2</th>
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<tbody>
<tr>
<td>053.10-053.19</td>
<td>344.1</td>
<td>437.8</td>
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<td>140.0-239.9</td>
<td>344.2</td>
<td>719.40-719.49</td>
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<td>344.30-344.32</td>
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<td>353.0-356.6</td>
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<td>342.10-342.12</td>
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<td>343.0-343.9</td>
<td>355.71</td>
<td>V58.49*</td>
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<td>344.00-344.09</td>
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</tr>
</tbody>
</table>

*Note that the appropriate ICD-9-CM code to bill for post-operative pain management is V58.49 (Other specified aftercare following surgery).

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
The appropriate code to bill for the fluoroscopic guidance component (if fluoroscopy is utilized) for these procedures codes (62310, 62311, 62318, and 62319) would be procedure code 76005: Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint nerve or sacroiliac joint), including neurolytic agent destruction.

It would not be appropriate to bill procedure code 72275 (Epidurography, radiological supervision and interpretation) for the fluoroscopy and injection of contrast material in addition to procedure codes 62310, 62311, 62318, and 62319. These codes state in their descriptors “with or without contrast (for either localization or epidurography)”. Therefore, the injection of contrast is included in the injection code. It would be appropriate to bill procedure code 72275 if epidurography is the only procedure being performed and if “radiological supervision and interpretation” by the radiologist was performed.

CPT codes 62310-62319 are for “single injections (not via an indwelling catheter),” and codes 62318-62319 are for “injection, including catheter placement, continuous infusion or intermittent bolus.” Therefore, billing any combination of these two sets of codes (62310-62311 and 62318-62319) would not be allowed for the same patient on the same date of service. There can be several scenarios in the case of epidural/subarachnoid injections used for post operative pain management. Each one has specific coding applications as detailed in the following circumstances:

- The catheter is used for the surgical anesthesia and then used post-operatively for pain management. In this case, it would be appropriate to bill the applicable anesthesia code for the procedure on the date of surgery and bill 01996 (daily management of epidural or subarachnoid drug administration) for subsequent days until the catheter is removed. It would not be appropriate to bill 62318 or 62319 in this case.

- The catheter is placed pre-operatively for post-operative pain management only. In this case, the patient received another form of anesthesia (e.g., general anesthesia) and an epidural/subarachnoid catheter is placed pre-operatively because the surgeon and/or anesthesiologist believes post-operative pain can reasonably be expected to be sufficient to require this level of pain management. In this situation, it would be appropriate to bill the applicable anesthesia code, as well as the appropriate injection code (62318 or 62319) for the placement of the epidural/subarachnoid catheter. The subsequent days that an injection is given through the catheter for pain management would then be billed using 01996 as above.

- The catheter is placed post-operatively for pain management. In this case, once the patient is awake and the surgeon and/or anesthesiologist feels that the post-operative pain is sufficient to require this level of pain control, then both the applicable anesthesia code and the appropriate injection code for the placement and injection of the epidural/subarachnoid injection, would be appropriate to bill. Subsequent days that an injection was given through the catheter would be billed using 01996 as above.

Note that the appropriate ICD-9-CM code to bill for acute post-operative pain management is V58.49 (Other specified aftercare following surgery).

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

In addition, if the procedure is performed due to a chronic pain condition, the medical record should clearly document the nature of the chronic pain condition. This should include the location, intensity, type of pain...
present, contributing factors (if any), duration of condition, and treatment regimes that have been utilized. Documentation should demonstrate failure of conservative management in the treatment of the patient’s condition.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 1 PCR B2000-170
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 11/20/2000
Explanation of Revision: An indication was added to allow for epidural/subarachnoid injections based on the indications identified in the Implantable Infusion Pump LMRP. In addition, the corresponding diagnoses for this indication were added.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 66982

Policy Number
66982

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Cataract Extraction

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HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
11/18/1996

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Cataract is defined as an opacity or loss of optical uniformity of the crystalline lens with cataract development located on a continuum extending from minimal changes of original transparency in the crystalline lens to the extreme stage of total opacity. Cataracts may be due to a variety of causes but are usually associated with aging. Age-related cataract (senile cataract) is by far the most common type of cataract. Other types of cataracts are childhood (both congenital and acquired), traumatic, complicated, toxic and after-cataract (secondary).

Most cataracts are not visible until they become dense enough (mature or hypermature) to cause blindness. However, a cataract in its earliest stages of development can be observed through a well-dilated pupil with an ophthalmoscope, loupe, or slit lamp. The ocular fundus becomes increasingly more difficult to visualize as the lens opacity becomes denser, until the fundus reflection is completely absent. At this stage, the cataract is usually mature and the pupil may be white. There is no medical treatment for cataract. Lens extraction either by intracapsular or extracapsular procedure is performed when visual impairment interferes with the patient’s normal activities.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider cataract surgery medically necessary and reasonable for the following conditions:

- Symptoms such as blurred vision, visual distortion, and/or glare with associated functional impairment.

Functional impairment due to cataracts refers to lost or diminished ability to perform everyday activities, participate in hobbies or other leisure-time activities,
or to work in one’s occupation. Several instruments such as the VF-14, the activities of daily vision scale and the visual activities questionnaire are available for assessing functional impairment related to cataract.

- Visual disability with Snellen acuity worse than 20/40 with impairment of ability to carry out needed or desired activities. The ocular exam should confirm that the best correctable visual acuity in the affected eye is worse than 20/40 and that the cataract is responsible for this.

- Visual disability with Snellen acuity of 20/40 or better. For patients with a Snellen acuity of 20/40 or better, the indicators are the same as for patients with Snellen acuity of worse than 20/40. In addition, documentation must support a visual impairment such as fluctuation of visual function because of glare or dim illumination; complaints of monocular diplopia or polyopia; visual disparity exists between the two eyes; or the patient needs but cannot obtain an unrestricted driving license.

- Lens-induced disease. Phacomorphic glaucoma, phacolytic glaucoma and other lens-induced diseases may require cataract surgery.

- Concomitant ocular disease that requires clear media. Cataract extraction may be required to adequately diagnose or treat other ocular conditions, such as diabetic retinopathy.

Surgery is not medically necessary just because the cataract is present.

Surgery should not be performed solely to improve vision under the following circumstances:

- The patient does not desire surgery,
- Glasses or visual aids provide satisfactory functional vision,
- The patient’s life-style is not compromised,
- The patient is medically unfit (e.g., conditions such as comatose patients, Organic Brain Syndrome, end stage alzheimers blind patients, etc. in which cataract surgery will not improve the patient’s independence).

It is not recommended that surgery be done on both eyes at the same time. The time interval should be based on the following factors:

- The patient is able to provide informed consent for surgery on the second eye after evaluating the visual results and postoperative course of surgery on the first eye.
- Adequate time has passed (3 weeks) to detect and treat the most immediate vision-threatening complications of cataract surgery.
- Vision in the operated-on eye has recovered sufficiently so that the patient is not at risk of injury due to functional impairment during second eye cataract surgery.

**HCPCS Section & Benefit Category**

Eye and Ocular Adnexa /Surgery

**CPT Codes**

66982
66983
66984

**Not Otherwise Classified Codes (NOC)**

N/A

**ICD-9-CM Codes that Support Medical Necessity**

N/A

**Diagnoses that Support Medical Necessity**

N/A

**ICD-9-CM Codes that DO NOT Support Medical Necessity**

N/A

**Diagnoses that DO NOT Support Medical Necessity**

N/A

**Reasons for Denial**

Cataract surgery performed for indications other than those considered medically necessary are considered routine, and, therefore noncovered.

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

**Noncovered ICD-9-CM Code(s)**

N/A

**Noncovered Diagnoses**

N/A

**Coding Guidelines**

When billing for cataract extraction, use appropriate RT or LT modifier.

**Documentation Requirements**

Documentation supporting medical necessity (e.g., office/progress notes) of the cataract surgery must contain:

- Visual acuity (best corrected Snellen chart)
- Symptomatology
- The use of conservative treatment including current refraction is no longer satisfactory
- Degree of functional impairment (This can be in any form; e.g., narrative or assessment tool as long as it supports how the cataract affects the patient’s ADL’s.)

**Utilization Guidelines**

N/A

**Other Comments**

Terms Defined:

Snellen Chart-a chart used to test visual acuity,

Diplopia-double vision,

Polyopia-multiple vision; perception of more than one image of the same object,

The White Paper on Cataract Surgery was developed by the American Academy of Ophthalmology and American Society of Cataract and Refractive Surgery. The purpose of this paper was to compare the AHCPR guidelines developed in 1993 with new development in the state of cataract surgery.

The AHCPR guidelines describe indications for cataract surgery based on two categories of visual acuity, 20/40 or better and 20/50 or worse. As the guideline highlighted, functional impairment which describes the actual impact on the patient’s function and quality of life is a critical measure to describe, both in terms of indications for
New developments in the assessing of functional impairment is the availability of several new instruments, which include the VF-14, the Activities of Daily Vision Scale and the Visual Activities Questionnaire. These measures provide valid and reliable information on the impact of everyday functioning of the patient that is not already reflected in the measurement of visual acuity.

Formal measures of functional status, or description of functional impairment gained through history taking are necessary, but not sufficient, for determining the need for surgery. The findings of the physical examination should corroborate that the cataract is the major contributing cause of the functional impairment, and that there is a reasonable expectation that managing the cataract will positively impact the patient’s functional activity. Therefore, visual acuity is not the sole determining factor, and should not be used as a threshold value.

**Sources of Information**

Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

**Medical Policy Procedures: 67221**

**Policy Number**
67221

**Contractor Name**
First Coast Service Options, Inc.

**Contractor Number**
00590

**Contractor Type**
Carrier

**LMRP Title**
Ocular Photodynamic Therapy (OPT) with Verteporfin

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**HCFA National Coverage Policy**
Medicare Carriers Manual, Section 2049

**Primary Geographic Jurisdiction**
Florida

**Secondary Geographic Jurisdiction**
N/A

**HCFA Region**
Region IV

**HCFA Consortium**
Southern

**Policy Effective Date**
03/19/2001

**Revision Effective Date**
N/A

**Revision Ending Effective Date**
N/A

**Advisory Committee Notes**

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from from the Ophthalmology Specialty.

**Start Date of Comment Period**
N/A

**Start Date of Notice Period**
02/01/2001

**Revision History**
Revision Number: 1
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

**Advance Notice Statement**
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

**Policy Ending Date**
N/A

**LMRP Description**
Ocular photodynamic therapy (OPT) is a form of treatment for the “wet” or exudative form of age-related macular degeneration. The wet form of macular degeneration involves the growth of abnormal blood vessels called choroidal neovascularization (CNV) beneath the retina resulting in leakage and bleeding. Without treatment, a majority of patients eventually develop scar tissue beneath the macula, which results in loss of central vision. The concept of OPT is to selectively close the abnormal blood vessels, eliminate the bleeding and leakage, and stabilize or improve the vision.

OPT is similar to traditional laser ablation in that abnormal blood vessels are destroyed; however, it is unique in that the low intensity laser activation of the drug verteporfin (VISUDYNE™) preserves the surrounding structures from destruction that is an unfortunate side effect of traditional thermal laser. This feature allows use of this treatment for preservation of vision when the CNV occurs close to the center of the macula.

OPT is a two-step process. In the first step, the patient receives an intravenous injection of verteporfin. The verteporfin circulates through the body and adheres to the walls of the abnormal blood vessels beneath the macula. A laser is then used to shine light into the back of the eye. When this light beam activates the verteporfin, there is closure of the blood vessel. Over time, the body is able to absorb the blood and fluid, which results in stabilization or improvement of visual function.

Over the course of 1-3 months, the blood vessels that have been treated with OPT typically open again and leakage may recur. Treatment is performed at three-month intervals if there is evidence of continued leakage from the blood vessels.
Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider OPT with verteporfin medically reasonable and necessary when performed for the following indications:

- For the treatment of age-related wet form macular degeneration in patients with predominantly classic or >50% classic subfoveal CNV.

Prior to initial verteporfin OPT treatment, documentation of the patient’s condition must include all of the following:

- Fluorescein angiographic evidence of predominantly classic or >50% classic subfoveal CNV secondary to age-related wet macular degeneration;
- CNV extending below the geometric center of the foveal avascular zone;
- Area of predominantly classic or >50% classic subfoveal CNV is at least fifty percent (50%) of the area of the total neovascular lesion;
- Snellen chart visual acuity of 20/40 through 20/800; and
- Age equal to or greater than 50 years.

Follow-up for recurrent leakage is generally expected to occur approximately every three months, to include fluorescein angiography and further treatment. It is expected that retreatment OPT with verteporfin will occur less frequently in subsequent years.

Prior to verteporfin OPT retreatment, documentation of the patient’s condition must include fluorescein angiographic evidence of current leakage from CNV.

Florida Medicare will not consider the performance of OPT with verteporfin medically reasonable and necessary when any of the following circumstances exist:

- Inability to obtain photographs and an adequate, legible fluorescein angiogram to document CNV (including difficulty with venous access) unless there is a documented history of fluorescein allergy;
- History of previous thermal laser in the geometric center of the fovea in the eye(s) to be treated;
- Active hepatitis or clinically significant liver disease;
- Porphyria or other porphyrin sensitivity; and
- There is no evidence of CNV leakage (as determined by fluorescein angiography).

HCPCS Section & Benefit Category
Surgery/ Eye and Ocular Adnexa

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>67221</td>
<td>Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion)</td>
</tr>
<tr>
<td>G0184</td>
<td>Destruction of localized lesion of choroid (for example, neovascularization); ocular photodynamic therapy (includes intravenous infusion), other eye</td>
</tr>
</tbody>
</table>

Not Otherwise Classified Codes (NOC)
J3490 Unclassified drugs (Verteporfin [Visudyne™])

ICD-9-CM Codes that Support Medical Necessity
362.52

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

The use of verteporfin with laser activation is the only form of OPT that is FDA-approved. Other drugs for OPT remain experimental, and therefore noncovered by Medicare.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
CPT code 67221 must be used for claims for OPT and includes the infusion of verteporfin and all other services required to perform OPT.

HCPCS code G0184 should only be billed when performing OPT on a second eye at the same session as the first eye.

HCPCS code J3490 must be used for the drug verteporfin (Visudyne™).

Claims submitted for OPT performed on both eyes on the same day will only receive a single reimbursement rate for verteporfin, as a single infusion is adequate for treatment of both eyes.

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure/operative report.

The documentation maintained by the performing physician should include the following:

- Evaluation and management exam including the most recent visual acuity; the name and total calculated drug dose (mg) of the photodynamic therapy drug administered; the patient’s body surface area on which the dose of the drug is based; and the laser spot size and greatest linear dimension of CNV lesion.
• Fluorescein angiogram or the digital angiogram. There should be an available copy used by the clinician to determine the size and location of the CNV lesion.
• Fluorescein angiography report, which should include the description of the lesion (e.g., predominantly classic, minimally classic, no classic).

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Society of Ophthalmology.

Carrier Advisory Committee Meeting held on August 19, 2000.

Start Date of Comment Period
08/11/2000

Start Date of Notice Period
02/01/2001

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 69210
Policy Number
69210

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Impacted Cerumen Removal

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HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
03/19/2001

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Cerumen, commonly known as earwax, is the product of desquamated skin mixed with secretions from the adenaxal glands of the external ear canal. Cerumen generally provides lubrication, acts as a vehicle for the removal of contaminants away from the tympanic membrane, and prevents desiccation of the epidermis with its associated fissuring.

Cerumen can accumulate and become impacted in the ear canal for a variety of reasons. Impacted cerumen can cause the patient to experience a sense of pressure or blockage and impairment of hearing.

Indications and Limitations of Coverage and/or Medical Necessity
Removal of impacted cerumen usually entails one or more of three methods of removal. The first two methods of cerumen removal must be either personally performed by the physician, or performed by the physician’s employees under the “incident to” provision.
• The first two methods of cerumen removal are methods of irrigation of the ear canal(s).
• The second method of cerumen removal involves the use of chemical solvents. The solvents are often used to soften the cerumen, which facilitates its removal.

The methods of cerumen removal listed above are considered part of the evaluation and management service, (procedure codes 99201-99357), and therefore, are not separately reimbursable with procedure code 69210.
• The third method of cerumen removal is manual disimpaction. This method is performed by the physician under binocular magnification and generally entails grasping the cerumen plug with forceps, application of suction, and/or extraction with a right-angle hook. In cases of severely impacted ears, injections of local anesthesia may be required.

For the purpose of this policy, binocular magnification visualization is defined as examination
of the ear(s) by a physician using an operating microscope. The patient is placed in an examination chair or on an examination table and the microscope is placed into a position that will enable the physician to use both hands to perform the necessary procedure on the ear(s). Hand held otoscopes and magnification glasses do not qualify as binocular vision.

Florida Medicare will consider only the manual disimpaction method of cerumen removal reimbursable as a separate procedure (69210).

HCPCS Section & Benefit Category
Auditory System/Surgery

CPT Codes
69210

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
380.4

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed by a method other than the one listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Medical Policy Procedures: 70370

Policy Number
70370

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Dysphagia/Swallowing Diagnosis and Therapy

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Society of Otolaryngology, the Florida Academy of Family Practice Physicians, and the Florida Society of Internal Medicine.

Carrier Advisory Committee Meeting held on May 13, 2000.

Start Date of Comment Period
05/05/2000

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: Original PCR B2001-061
Start Date of Comment Period: 05/05/2000
Start Date of Notice Period: 02/01/2001

2nd Qtr 2001 Update!

Original Effective Date: 03/19/2001

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

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HCFA National Coverage Policy
Medicare Carrier Manual, Section 2070.4
HCFA Letter, June 13, 1996, Modified Barium Swallow Studies and Mobile Video Fluoroscopy X-rays

Primary Geographic Jurisdiction
Florida
Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
10/28/1996

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Dysphagia/swallowing therapy is a medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury. Phases of swallowing addressed include oral, pharyngeal, and/or esophageal (upper one third) phases of swallowing.

The diagnosis of dysphagia, or difficulties in swallowing, requires an extensive evaluation by the physician. Many difficulties can be identified and treated based on the findings of this examination alone. In some cases, more extensive evaluations are required using a variety of studies such as echography and modified barium swallow studies and an evaluation by a swallowing therapist.

The treatment of dysphagia/swallowing difficulties may include simple recommendations for such things as intake consistency or positioning, or may require a therapeutic regime targeted at the attainment of functional improvement.

Indications and Limitations of Coverage and/or Medical Necessity

Dysphagia/Swallowing Therapy:

Each of the following conditions for coverage of service must be met:

1. The patient is under the care of a physician.
2. The attending physician may be the patient’s private physician or a physician associated with an institution. There must be evidence in the clinical record maintained by the therapist that the patient has been seen by the physician at least every 60 days and the therapist must indicate the name of the physician and date the patient was last seen by the physician.
3. The physician must establish a preliminary diagnosis addressing the symptoms associated with the dysphagia. This preliminary diagnosis should address the treatability of the patient. Collaboration between the physician and the speech language pathologist or other dysphagia therapist is necessary to establish the medical necessity for the dysphagia evaluation and/or treatment.
4. There must be supporting documentation in the medical record to demonstrate the need for a dysphagia evaluation such as a recent significant change in swallowing function.

   One or more of the following conditions must be present:
   • History of aspiration problems or definite risk of aspiration.
   • Presence of oral motor disorder.
   • Impaired salivary gland performance and/or presence of local structural lesions in the pharynx in marked oropharyngeal swallowing difficulties.
   • Dyscoordination, sensation loss, postural difficulties, or other neuromotor disturbances affecting oropharyngeal abilities necessary to close the buccal cavity and/or bite, chew, suck, shape, and squeeze the food bolus into the upper esophagus, while protecting the airway.
   • Post surgical reaction.
   • Significant weight loss with loss directly related to reduced oral intake as a consequence of dysphagia.
   • Existence of other conditions such as: presence of tracheotomy tube, nasogastric feeding tube, endotracheal tube, or ventilator reduced or inadequate laryngeal elevation, labial closure, velopharyngeal closure, laryngeal closure, or pharyngeal peristalsis and cricopharyngeal disjunction.

5. Assessment:

   Professional assessments including bedside evaluation administered by a qualified dysphagia therapist must document history, current status, and clinical observations such as:
   • presence of feeding tube
   • presence of tracheotomy tube
   • paralysis
   • coughing and/or choking
   • oral motor structure and function
   • muscle tone
   • oral sensitivity
   • positioning
   • oropharyngeal reflexes
   • swallowing function
   • oral infections and lesions
   • medications to include psychopharmacological drugs

6. Treatability:

   The attending physician and/or the dysphagia therapist must address the treatability of the patient in terms of the patient’s:
   • level of alertness
   • ability to cooperate
   • ability to retain new learning
   • cognitive status
   • medical stability
   • psychological stability

7. Videofluroscopy or other visual instrumental assessments should be conducted when oral or pharyngeal disorders are suspected. Documentation must establish that an exact diagnosis cannot be substantiated through an oral exam and that there is a question as to whether aspiration is occurring. The videofluoroscopic assessment is usually conducted and interpreted by a radiologist with the assistance and
input from the physician and/or individual disciplines. The assessment and final analysis and interpretation should include a definitive diagnosis, identification of the swallowing phase(s) affected, and a recommended treatment plan.

8. The therapy must be furnished under the written plan of treatment, with measurable goals and time frames established by the physician or therapist caring for the patient.

9. The services must be of such a level of complexity and sophistication that they can only be performed by a qualified dysphagia therapist. A qualified speech/language pathologist for treatment coverage purposes is an individual who is licensed as a speech/language pathologist by the state in which they are practicing, has a minimum of a masters degree, holds a certificate of clinical competence and is prepared to produce evidence of special preparation in the field of dysphagia.

10. Reasons for denial of diagnostic procedures:

- Documentation does not support their need in making a diagnosis or in defining the etiology of the patient’s condition.
- Modified Barium Swallow studies (70370, 70371, and 74230) are not covered when performed on a mobile basis.

11. Reasons for denial of therapy:

- Services are not reasonable and/or medically necessary. (Patient is unable to meet treatability criteria.)
- Routine feeding, which can be completed by support staff and/or family members.
- Exercises that can be carried out by the patient, support staff, and/or family members.
- The level of treatment does not require the skills of a trained dysphagia specialist.
- Treatment provided is maintaining the patient’s functioning at the level to which it has been restored.
- Daily visits do not decrease as patient improves.
- Treatment addresses the esophageal (lower two-thirds) phase of swallowing. Esophageal dysphagia is difficulty in passing food from the esophagus to the stomach. If peristalsis is ineffective, patients may complain of food “sticking”, have more difficulty with solids than liquids, and/or experience reflux or regurgitation if they lie down too soon after meals. This is a common problem in geriatric patients and does not generally respond to behavioral swallowing therapy techniques and would not be approved.
- Treatment is provided by an individual therapist who is unable to present documentation of training qualifications.

HCPCS Section & Benefit Category
Radiology/Diagnostic Radiology
Radiology/Diagnostic Ultrasound
Medicine/Special Otorhinolaryngologic Services

CPT/HCPCS Codes
70370  70371  74230  92511  92525  92526  76000  76001
G0195  G0196

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Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
N/A

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
HCPCS codes 70370, 70371, and 74230 are covered only in the places of services listed below, and never when performed on a mobile basis or in the absence of physician supervision:

- Office (11)
- Inpatient hospital (21)
- Outpatient hospital (22)
- Emergency room-hospital (23)
- Comprehensive inpatient facility (61)
- Comprehensive outpatient facility (62)

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
N/A

Noncovered Diagnoses
N/A

Coding Guidelines
CPT codes 70370, 70371, and 74230 describe complete procedures and should not be billed more than one time on the same patient on the same day. Only one of the stated procedure codes should be billed per patient per day.

Other fluoroscopy codes, including the following, are not allowed in addition to the swallow studies as each of the swallow study codes already contain the fluoroscopy component:

76000 Fluoroscopy (separate procedure), up to one hour physician time, other than 71023 or 71034 (e.g., cardiac fluoroscopy),

76001 Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy).

Effective for services performed on or after January 1, 2001, procedure code 92525 is not valid for Medicare purposes. HCPCS codes G0195 or G0196 should be billed.

Documentation Requirements
Medical record documentation such as office/progress notes, etc. must indicate that the physician’s evaluation demonstrated a need for any further diagnostic testing related to dysphagia/swallowing difficulties, as well as a need for any treatment.
Specific plans of treatment should be developed in conjunction with a qualified therapist, and include a statement of functional improvement expected, specific goals for therapy, and the specific interventions to be used in achieving the goals. The frequency, type and duration of these interventions must also be specified.

Finally, each intervention must be documented as having been performed, along with the patient’s progress and reaction to the intervention.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
N/A

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the ENT and Family Practice Specialty.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 2
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
Revised Effective Date: 01/01/2001
Explanation of Revision: A revision is necessary to reflect the status changes based on Change Request 1470 (Transmittal B-00-75). Procedure Code 92525 was changed from Noncovered to not valid for Medicare purposes.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 70544

Policy Number
70544

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Magnetic Resonance Angiography (MRA)

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HCFA National Coverage Policy
Coverage Issues Manual, Section 50-14

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/15/1995

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Magnetic Resonance Angiography (MRA) is an application of magnetic resonance (MR) imaging that provides visualization of blood flow, as well as images of normal and diseased blood vessels. MRA techniques are typically noninvasive because they do not require the use of contrast media. While contrast media may sometimes be used to enhance the images obtained in MRA, the use of these agents is not necessary. As a result, MRA is an imaging alternative for patients who cannot tolerate contrast media.

Indications and Limitations of Coverage and/or Medical Necessity
Although MRA appears to be a rapidly developing technology, the clinical safety and effectiveness of this procedure for all anatomical regions has not been proven. As a result Medicare will provide coverage on a limited basis. Below are the indications for which Medicare coverage is allowed for MRA. All other uses of MRA will not be covered.

Head and Neck (for services performed before 7/1/99) [ (procedure codes 70544-70549) ]
Medicare will provide coverage for the evaluation of the carotid vessels in the head and neck when all of the following conditions are met:
- For a patient who has a positive ultrasonography; and
- When performed on patients with symptoms associated with carotid stenosis for which surgery may be found to be appropriate based on the results of these tests.

It should be noted that physicians may choose either contrast angiography (CA) or MRA as diagnostic tests after a positive ultrasound for their patients. MRA is not performed routinely as an adjunct to CA. CA furnished in addition to MRA might be appropriate only when the results from the MRA and the ultrasound are incongruent or inconclusive.
Head and Neck (for services performed on or after 7/1/99) [ (procedure codes 70544-70549) ]
Medicare will provide coverage for the evaluation of the vessels in the head and neck when all of the following conditions are met:

- To evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries, or the venous sinuses; and
- Be performed on patients with conditions of the head and neck for which surgery is anticipated and may be found to be appropriate based on the MRA. These conditions include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion or thrombosis.

MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

Chest (procedure code 71555)
Medicare will cover MRA of the chest for the following indications:

For the Diagnosis of Pulmonary Embolism
Medicare will consider MRA of the chest for diagnosing a suspected pulmonary embolism to be a covered service when the following criteria have been met:

- A patient is suspected of having a pulmonary embolism and it is contraindicated for the patient to receive intravascular iodinated contrast material.
- A patient is allergic to iodinated contrast material and would face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography.

For Pre-operative or Post-operative Evaluation of Thoracic Aortic Dissection and Aneurysm
Medicare will consider MRA of the chest for the evaluation of thoracic aortic dissection and aneurysm to be a covered service when the following criteria are met:

- Depending on the clinical presentation, MRA may be used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT.
- Either MRA or CA may be used as a diagnostic test for thoracic aortic dissection and aneurysm, but not both tests on a routine basis.
- If both MRA and CA of the chest are used to diagnose thoracic aortic dissection and aneurysm, the physician must demonstrate the medical need for performing both tests.

Peripheral Arteries of Lower Extremities [ (procedure code 73725) ]
Studies have proven that MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities. Effective May 1, 1997, Medicare will consider MRA of the arteries of the lower extremities to be a covered service only when the following criteria have been met:

Either MRA or CA may be performed to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful in some cases, such as:

- A patient has had CA and this test was unable to identify a viable run-off for bypass. When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel.
- A patient has had MRA, but the results are inconclusive.

Abdomen (procedure code 74185)
Studies have proven that MRA is considered a reliable diagnostic tool for the preoperative evaluation of patients who will undergo elective abdominal aortic aneurysm (AAA) repair. In addition, scientific data has revealed that MRA is considered comparable to CA in determining the extent of AAA, as well as evaluation of aortoiliac occlusion disease and renal artery pathology that may be necessary in the surgical planning for AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative angiography is not necessary then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage or arterial injury. As with coverage of MRA for other anatomical sites, Medicare will provide coverage for either MRA or CA and not both tests on a routine basis.

The physician may choose between CA or MRA for preoperative imaging, after other tests such as computed tomography (CT) or ultrasound have been used to diagnose AAA and evaluate aneurysm size over time. However, both MRA and CA may be used when the physician can demonstrate the medical need for both tests to be performed, such as when a follow-up CA is necessary to clarify renal artery pathology, which might not be diagnosed definitively by an initial MRA.

HCPCS Section & Benefit Category
Radiology/Diagnostic Radiology

CPT Codes
70544  70547  70549  73725
70545  70548  71555  74185
70546

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
MRA of head and neck ( procedure codes 70544-70549 )

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<tr>
<td>094.89</td>
<td>Aorta and iliac arteries</td>
<td>430</td>
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<td>Thoracic aortic dissection and aneurysm</td>
<td>431</td>
<td>437.4</td>
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<td>Abdominal aortic aneurysm</td>
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<td>Thoracic aortic aneurysm</td>
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<td>227.5</td>
<td>Abdominal aortic aneurysm</td>
<td>433.00-433.91</td>
<td>446.5</td>
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<td>Thoracic aortic aneurysm</td>
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<td>325</td>
<td>MRA of chest</td>
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MRA of chest (procedure code 71555)

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<td>416.9</td>
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</tbody>
</table>
MRA of peripheral arteries of lower extremities
(procedure code 73725)
250.70-250.73  442.3  443.89
440.20-440.29  443.1  443.9
440.30-440.32  443.81  444.22
MRA of abdomen (procedure code 74185)
441.02  441.4  441.9
441.03  441.7

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

HCFA considers CPT codes 72159, 72198, and 73225 to be noncovered by Medicare:

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Documentation Requirements
Documentation maintained in the patient’s file must indicate the medical necessity of this procedure. All coverage criteria listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section must be documented in the patient’s medical record, as well as a hard copy of the procedure results and made available to Medicare upon request. This information can generally be found in the office/progress notes, history and physical, and/or operative notes.

If the provider of the magnetic resonance angiography study is other than the ordering/referring physician, the provider of the service must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician’s order for the studies. The physician must state the reason for the MRA in his order for the test.

MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests. The medical record must clearly document the medical necessity of performing both tests.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Radiological Society, Inc.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 9  PCR B2001-017
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
2nd Qtr 2001 Update!

Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 70551
Policy Number
70551

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Magnetic Resonance Imaging of the Brain

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HCFA National Coverage Policy
Coverage Issues Manual, Section 50-13

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A
LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
04/17/1997

Revision Effective Date
02/05/2001

Revision Ending Effective Date
02/04/2001

Policy Ending Date
N/A

LMRP Description
Magnetic Resonance Imaging (MRI) is used to diagnose a variety of central nervous system disorders. Unlike computed tomography (CT) scanning, MRI does not make use of ionizing radiation or require iodinated contrast material to distinguish normal from pathologic tissue. Rather, the difference in the number of protons contained within hydrogen-rich molecules in the body (water, proteins, lipids, and other macromolecules) determines recorded image qualities and makes possible the distinction of white from gray matter, tumor from normal tissue, and flowing blood within vascular structures.

MRI provides superior tissue contrast when compared to CT, is able to image in multiple planes, is not affected by bone artifact, provides vascular imaging capability, and makes use of safer contrast media (gadolinium chelate agents). Its major disadvantage over CT is the longer scanning time required for study, making it less useful for emergency evaluations of acute bleeding or for unstable patients. Because a powerful magnetic field is required to obtain an MRI, patients with ferromagnetic materials in place may not be able to undergo MRI study. These include patients with cardiac pacemakers, implanted neurostimulators, cochlear implants, metal in the eye and older ferromagnetic intracranial aneurysm clips. All of these may be potentially displaced when exposed to the powerful magnetic fields used in MRI.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Magnetic Resonance Imaging of the Brain medically reasonable and necessary when used to aid in the diagnosis of lesions of the brain and to assist in therapeutic decision making in the following conditions:

- For detecting or evaluating extra-axial tumors, A-V malformations, cavernous hemangiomas, small intracranial aneurysms, cranial nerve lesions, demyelination disorders including multiple sclerosis, lesions near dense bone, acoustic neuromas, pituitary lesions, and brain radiation injuries;
- For development abnormalities of the brain including neuroectodermal dysplasia;
- Subacute central nervous system hemorrhage or hematoma;
- Acute cerebrovascular accidents;
- Complex partial seizures, seizures refractory to therapy, temporal lobe epilepsy, or other atypical seizure disorders;
- MRI is usually not the procedure of choice in patients who have acute head trauma, acute intracranial bleeding, or investigation of skull fracture or other bone abnormality, or as follow-up for hydrocephalus. However, a MRI may be necessary in patients whose presentation indicates a focal problem or who have had a recent significant change in symptomatology;
- For brain infections;
- Where soft tissue contrast is necessary;
- When bone artifacts limit CT, or coronal, coronosagittal or parasagittal images are desired;
- For procedures in which iodinated contrast material are contraindicated.

HCPCS Section & Benefit Category
Radiology/Diagnostic Radiology

CPT Codes
70551
70552
70553

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

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<th>Code</th>
<th>Description</th>
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<tr>
<td>006.5</td>
<td>MRI, head and neck, cervical spine, axial views</td>
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<tr>
<td>013.00-013.36</td>
<td>MRI, head and neck, sagittal views</td>
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<tr>
<td>013.60-013.96</td>
<td>MRI, head and neck, coronal views</td>
</tr>
<tr>
<td>036.0-036.2</td>
<td>MRI, head and neck, axial views</td>
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<td>036.3</td>
<td>MRI, head and neck, axial views with contrast media</td>
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<td>042</td>
<td>MRI, head and neck, axial views with contrast media</td>
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<tr>
<td>046.0-046.9</td>
<td>MRI, head and neck, axial views with contrast media, bone suppression</td>
</tr>
<tr>
<td>047.0-047.9</td>
<td>MRI, head and neck, coronal views with contrast media</td>
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<tr>
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<td>MRI, head and neck, parasagittal views with contrast media</td>
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<td>052.0</td>
<td>MRI, head and neck, sagittal views with contrast media</td>
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<td>053.0</td>
<td>MRI, head and neck, axial views with contrast media</td>
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<td>054.3</td>
<td>MRI, head and neck, axial views with contrast media</td>
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<td>054.72</td>
<td>MRI, head and neck, axial views with contrast media, bone suppression</td>
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<td>MRI, head and neck, coronal views with contrast media</td>
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<td>056.01</td>
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ICD-9-CM Codes that Support Medical Necessity:

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Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
Magnetic Resonance Imaging is considered investigational when medical records document the service was performed only for one of the following:

- measurement of blood flow and spectroscopy,
- imaging of cortical bone and calcifications, and
- procedures involving spatial resolution of bone or calcifications.

When Magnetic Resonance Imaging is used for an investigational purpose, an acceptable advance notice of Medicare’s denial of payment must be given to the patient when the provider does not want to accept financial responsibility for the service.

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines

- If the procedure is performed using contrast only, procedure code 70552 should be billed. If the procedure is performed initially without contrast, followed by contrast then procedure code 70553 should be billed. Procedure codes 70551, 70552, and/or 70553 should not be billed on the same day for the same patient.
- The appropriate ICD-9-CM for the covered procedure must be submitted as the line diagnosis on the claim.
- In general, it is not medically necessary to perform myelography, CT examinations, and MRI examinations for evaluation of the same condition on the same day. The medical record should document the necessity for evaluations in addition to a MRI.

Documentation Requirements

The medical record should support the medical necessity and frequency of this treatment. Documentation including office/progress notes, history and physical, and a copy of the MRI report should be maintained in the patient’s medical record.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information

Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

Carrier Advisory Committee Meeting held on September 28, 1996.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History

Revision Number: 4
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
2nd Qtr 2001 Update!

Revised Effective Date: 02/05/2001
Explanation of Revision: A revision was made to add ICD-9-CM code range 162.0-162.9 to the policy.

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Medical Policy Procedures: 72192

Policy Number
72192

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Computed Tomography of the Pelvis

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-12

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A
Computed Tomography of the Pelvis (CT Scan of the Pelvis) is a noninvasive yet accurate X-ray procedure which results in images from passing X-rays through an organ at many angles. The variation and density of each tissue allows for variable penetration of the X-rays. Each density is computed by utilizing a coefficient (or numeric value) which is digitally computed into shades of gray. These shades of gray are then displayed on a monitor as thousands of dots in various shades.

The pelvis is a basin-like structure that supports the spinal column and rests on the lower limbs. The “true pelvis” is defined as that portion of the pelvis situated below and behind the pelvic brim.

The CT scan of the pelvic area includes the bladder, prostate, ovaries, uterus, lower retroperitoneum and iliac lymph node chains. CT scans are generally performed to study the pelvic viscera. In males, this includes the bladder and prostate and in females, the bladder, uterus and adnexa. The CT scan of the pelvis is useful in evaluating cysts, tumors, masses, metastasis to one or more of these organs, and iliac lymph nodes. Intravenous contrast material may be administered when enhanced views are needed.

**Indications and Limitations of Coverage and/or Medical Necessity**

Florida Medicare will consider a CT scan of the pelvis medically necessary and reasonable under the following conditions:

- To evaluate cysts, tumors, or masses of the pelvic structure (i.e., that which lies at or below the pelvic brim, or true pelvis);
- To evaluate metastasis of primary cancers to this region;
- To evaluate inflammatory processes of this region;
- To evaluate abnormalities of pelvic vascular structures;
- To evaluate lymphadenopathies of this region;
- To evaluate lower abdominal, generalized abdominal or pelvic pain;
- To evaluate other genitourinary disorders in which the physician can not make a diagnosis on physical examination and/or by ultrasound;
- To evaluate trauma to the pelvic structure/organisms; and/or
- To evaluate the effectiveness of a radiation treatment plan.
the spinal canal and rests on the lower limbs. Melloni (1985) describes the pelvis as a basin-like structure that supports retroperitoneum, and iliac lymph nodes. According to Golish (1994), a CT scan of the pelvic area includes the bladder, prostate, ovaries, uterus, lower retroperitoneum, and iliac lymph nodes. Melloni (1985) describes the pelvis as a basin-like structure that supports the spinal canal and rests on the lower limbs.

In addition, the “true pelvis” is described as that lying below the pelvic brim. Therefore, according to Gray’s Anatomy (1975), the male pelvic region includes the bladder and prostate and the female pelvic region includes the bladder, uterus and adnexa. Also, the rectum, anal canal, and anus are seen retroperitoneally. In addition, a portion of the sigmoid flexure may be viewed with the CT scan of the pelvis. Moreover, a portion of the ileum may be viewed, particularly in females (Gray’s Anatomy, 1975).

According to MacKay (1996), in some cases, ultrasound, or echography, can identify a lesion or mass and the CT scan of the pelvis is used for staging these tumors and/or when ultrasound results are suboptimal.

According to ACR (1995), CT scans of the pelvis are generally indicated to evaluate pain, masses, cysts, malignancies, inflammatory processes, trauma, treatment planning for radiation therapy, clarification of findings from other imaging studies and/or abnormal laboratory values.

According to the Coverage Issues Manual (CIM), Computerized Tomography is covered if medical and scientific literature and opinion support the effective use of a scan for the condition, the scan is reasonable and necessary and performed with equipment which is known to the Food and Drug Administration (FDA) and is in the full market release phase of development. According to CIM, there is no general rule that requires other diagnostic tests be performed before CT scanning is done. However, CIM further states that in individual cases the contractor’s medical staff may determine that the use of a CT scan as the initial diagnostic test was not medically necessary and reasonable because it was not supported by the patients symptoms or complaints.

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Radiologic Society.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 6
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 02/05/2001
Explanation of Revision: A revision was made to add ICD-9-CM codes 820.00-820.99, 867.0-867.9 and 902.81-902.9.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
If the procedure is performed using contrast only, procedure code 72193 should be billed. If the procedure is performed initially without contrast, followed by contrast then procedure code 72194 should be billed. Procedure codes 72192, 72193 and/or 72194 should not be billed on the same day for the same patient.

Documentation Requirements
The reason for the procedure should be documented in the physician’s progress note. Also, test results should be included in the documentation. In addition, if the CT scan is the primary diagnostic tool and physical examination and/or another test, such as echography, could have been performed to determine the patient’s diagnosis or status, the reason for utilizing the CT scan should also be documented. This information can usually be found in the office notes, facility progress notes, history and physical and/or test results.

If the provider of service is other than the ordering/refering physician, that provider must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/refering physician’s order for the studies. The physician must state the clinical indication/medical necessity for the study in his order for the test.

Utilization Guidelines
N/A

Other Comments
According to Golish (1994), a CT scan of the pelvic area includes the bladder, prostate, ovaries, uterus, lower retroperitoneum, and iliac lymph nodes. Melloni (1985) describes the pelvis as a basin-like structure that supports the spinal canal and rests on the lower limbs.

According to MacKay (1996), in some cases, ultrasound, or echography, can identify a lesion or mass and the CT scan of the pelvis is used for staging these tumors and/or when ultrasound results are suboptimal.

According to ACR (1995), CT scans of the pelvis are generally indicated to evaluate pain, masses, cysts, malignancies, inflammatory processes, trauma, treatment planning for radiation therapy, clarification of findings from other imaging studies and/or abnormal laboratory values.

According to the Coverage Issues Manual (CIM), Computerized Tomography is covered if medical and scientific literature and opinion support the effective use of a scan for the condition, the scan is reasonable and necessary and performed with equipment which is known to the Food and Drug Administration (FDA) and is in the full market release phase of development. According to CIM, there is no general rule that requires other diagnostic tests be performed before CT scanning is done. However, CIM further states that in individual cases the contractor’s medical staff may determine that the use of a CT scan as the initial diagnostic test was not medically necessary and reasonable because it was not supported by the patients symptoms or complaints.

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
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Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 6
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 02/05/2001
Explanation of Revision: A revision was made to add ICD-9-CM codes 820.00-820.99, 867.0-867.9 and 902.81-902.9.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
The LMRP for Magnetic Resonance Imaging (MRI) of Any Joint of the Lower Extremities (policy number 73721) was published in the 1st Quarter 2001 Medicare B Update! (pages 67-69). The annual HCPCS update for 2001 revises the descriptor for CPT code 73721, and adds two additional codes to the policy:

73721 Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material
73722 with contrast material(s)
73723 without contrast material(s), followed by contrast material(s) and further sequences

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All requirements listed in the policy apply to these new and revised codes. For specific information, please refer to the “ICD-9-CM Codes that Support Medical Necessity,” “Coding Guidelines,” “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the 1st Quarter 2001 Update!

Medical Policy Procedures: 80100

Policy Number 80100

Contractor Name First Coast Service Options, Inc.

Contractor Number 00590

Contractor Type Carrier

LMRP Title Qualitative Drug Screen

AMA CPT Copyright Statement CPT codes, descriptions, and other data only are copyright 1998 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Apply.

HCFA National Coverage Policy N/A

Primary Geographic Jurisdiction Florida

Secondary Geographic Jurisdiction N/A

HCFA Region Region IV

HCFA Consortium Southern

Policy Effective Date 08/16/1999

Revision Effective Date 01/01/2001

Revision Ending Effective Date 12/31/2000

Policy Ending Date N/A

LMRP Description A qualitative drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad qualitative screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants.

Current methods of drug analysis include chromatography, immunoassay, chemical (“spot”) tests, and spectrometry. Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by qualitative screen, followed by confirmation with a second method.

Examples of drugs or classes of drugs that are commonly assayed by qualitative screen, followed by confirmation with a second method, are: Alcohols, Amphetamines, Barbiturates, Benzodiazepines, Cocaine and Metabolites, Methadones, Methaqualones, Opiates, Phencyclidines, Phenothiazines, Propoxyphenes, Tetrahydrocannabinoids, and Tricyclic Antidepressants.

A qualitative drug screen may be indicated when the history is unreliable, with a multiple-drug ingestion, with a patient in delirium or coma, for the identification of specific drugs, and to indicate when antagonists may be used.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider performance of a qualitative drug screen medically reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:

• Unexplained coma;
• Unexplained altered mental status;
• Severe or unexplained cardiovascular instability (cardiotoxicity);
• Unexplained metabolic or respiratory acidosis;
• Unexplained head trauma with neurological signs and symptoms;
• Suspected history of substance abuse; and/or
• Seizures with an undetermined history.

Additionally, a qualitative drug screen will be considered medically reasonable and necessary for patients receiving active treatment for substance abuse when the patient presents with clinical signs and/or symptoms of noncompliance (e.g., feelings of euphoria, panic, mood swings). Providers must report ICD-9-CM code 304.90 for this coverage indication.
A qualitative drug screen is not medically reasonable or necessary under the following circumstances:

- In known overdose cases when the patient is asymptomatic (responsive to verbal stimuli, and has no seizures, hypoventilation, or cardiac abnormalities other than sinus tachycardia after several hours of observation);
- When the clinical picture is consistent with the reported history;
- To screen for the same drug with both a blood and a urine specimen simultaneously;
- To routinely monitor substance abuse compliance (i.e., the patient does not present with clinical signs and/or symptoms indicative of noncompliance);
- For medicolegal purposes (i.e., court-ordered drug screening); or
- For employment purposes (i.e., as a pre-requisite for employment or as a means for continuation of employment).

HCPCS Section & Benefit Category
Pathology and Laboratory/Drug Testing

CPT Codes
80100
80101
80102

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
276.2      780.01
304.90     780.09
345.90-345.91  977.9

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
The codes used to report qualitative drug testing distinguish between screening tests (80100 and 80101) and confirmatory testing (80102). The screening tests are further distinguished by the methods used to analyze multiple drug classes (80100) and those that test for a single drug class (80101).

The codes are intended to distinguish among analytical methods rather than the platform or instrumentation on which a particular method is run.

For example, chromatography, which can identify multiple drug classes, is coded using 80100 (when used in drug screening). For code 80100, each combination of stationary and mobile phase is to be counted as one procedure. For example, if screening for three drugs by chromatography requires one stationary phase with three mobile phases, report 80100 three times. However, if multiple drugs can be detected using a single analysis (e.g., one stationary phase with one mobile phase), report 80100 only once.

Immunoassays, which are used to identify single drug classes, should be coded using 80101 (when used in drug screening), whether the test is performed using a random access analyzer, a single analyte test kit, or a multiple analyte test kit. For procedure code 80101, each single drug class method tested and reported is to be counted as one drug class. For example, if a sample is aliquoted to five wells and separate class-specific immunoassays are run on each of the five wells and reported separately, report 80101 five times. Similarly, if a sample is run on a rapid assay kit comprising five class-specific immunoassays in a single kit, and the five classes are reported separately, code 80101 should be reported five times.

Use procedure code 80102 for each procedure necessary for confirmation. For example, if confirmation of three drugs by chromatography requires three stationary or mobile phases, bill 80102 three times. However, if multiple drugs can be confirmed using a single analysis, bill 80102 only once.

For quantitation of drugs screened, use the appropriate code (80150-80299 or 82000-84999).

Documentation Requirements
Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering physician/referring physician must indicate the medical necessity for performing a qualitative drug screen. Additionally, a copy of the lab results should be maintained in the medical records.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician’s order for the qualitative drug screen. The physician must state the clinical indication/medical necessity for the qualitative drug screen in his order for the test.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.
Advisory Committee Notes
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Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Medical Policy Procedures: 82105
Policy Number
82105

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Tumor Markers

AMA CPT Copyright Statement
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HCFA National Coverage Policy
Program Memorandum 536 A/B

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
08/25/1997

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Tumor markers are hormones, enzymes, or antigens produced by tumor cells and measurable in the blood or in some cases in the urine (e.g., bladder tumor associated antigens) of persons with malignancies. Tumor markers are measured by monoclonal antibodies designed to identify specific antigens. These tumor markers may reflect tumor size and grade and may be helpful in monitoring response to treatment. However, tumor markers are not useful for making a differential diagnosis of cancer since the sensitivity and specificity of these tests make it unreliable.

Revision History
Revision Number: 2
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS Update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

Indications and Limitations of Coverage and/or Medical Necessity
Alpha-fetoprotein; serum (procedure code 82105)
Florida Medicare will consider Alpha-fetoprotein; serum to be medically reasonable and necessary for:
• Evaluating the extent of involvement of hepatocellular carcinoma and germ cell tumors of the testis, ovary and extragonadal sites;
• Choosing therapy and predicting tumor behavior (prognosis); and/or
• Predicting effects of therapy and detecting recurrent cancer of hepatocellular carcinoma and germ cell tumors of the testis, ovary, and extragonadal sites.

Gonadotropin, Chorionic (hCG) (procedure codes 84702-84703)
Gonadotropin is a glycoprotein hormone which is normally produced by the developing placenta and aberrantly produced by gestational trophoblastic tumors, seminomatous and nonseminomatous testis cancer and ovarian tumors.

hCG is considered medically reasonable and necessary for:
• Evaluating the extent of involvement of specific types of cancer (see covered ICD-9-CM list); and/or
• Monitoring therapy response and evaluating the patient’s prognosis.

CA 125 (procedure code 86304)
The cancer antigen CA 125 is recognized by a monoclonal antibody OC-125. It is increased in most patients with advanced, nonmucinous (serous) ovarian cancer.

CA 125 is a covered service for patients with ovarian cancer (see covered ICD-9-CM list). CA 125 is considered investigational for diagnoses other than ovarian cancer.

CA 125 is not covered for making a differential diagnosis of pelvic masses since the sensitivity and specificity of the test makes it unreliable.

CA 125 is advocated for prognostic information. When measured serially, it may also be useful in the detection of relapse and as a monitor of patient response to chemotherapeutic agents.

CA27.29 (procedure code 86300)
The cancer antigen CA27.29 is a mucinous glycoprotein that can be detected by monoclonal antibodies. The CA27.29 marker is a tumor-associated marker available for monitoring the treatment and recurrence of carcinoma of the breast.
Florida Medicare will consider CA27.29 to be medically reasonable and necessary for the following conditions:

- CA 27.29 is used as an aid to predict recurrent breast cancer in patients with previously treated Stage II or Stage III disease; or
- CA 27.29 is used as an aid in monitoring response to therapy in patients with Stage IV breast cancer. A partial or complete response to treatment will be confirmed by declining levels. Likewise, a persistent rise of CA 27.29 levels despite therapy strongly suggests progressive disease.

Additionally, only those tests which are FDA approved, are covered by Medicare.

CA27.29 is not indicated as a screening test.

### CA15-3 (procedure code 86300)

The mucin glycoprotein-detecting assay CA 15-3 is a valuable tool for monitoring the course of disease in breast cancer patients. Assays of CA15-3 are based on the use of two monoclonal antibodies to polymorphic epithelial mucin (PEM).

Florida Medicare will consider CA15-3 to be medically reasonable and necessary for the following condition:

- To aid in the management of Stage II and Stage III breast cancer patients. Serial testing for patient CA15-3 assay values should be used in conjunction with other clinical methods for monitoring breast cancer.

Additionally, only those tests which are FDA approved, are covered by Medicare.

CA15-3 is not indicated as a screening test.

### Bladder Tumor Antigen (procedure code 86294)

There are immunoassay devices that use monoclonal antibodies to detect the presence of bladder tumor associated antigens in the urine of persons diagnosed with bladder cancer.

Florida Medicare will consider testing for bladder tumor antigens to be medically reasonable and necessary for the following condition:

- To be used with standard cystoscopic examination as an aid in the management of bladder cancer.

Testing for bladder tumor antigens is not indicated as a screening test for bladder cancer. Coverage may only be extended for its use in patients with a prior or known diagnosis of bladder cancer, for eradication of the cancer, or recurrences after eradication.

Evaluation of bladder tumor antigen has been proposed as an alternative to urine cytology; therefore, there is no medical necessity for the simultaneous performance of both tests.

### ICD-9-CM Codes that Support Medical Necessity

#### Alpha-fetoprotein (procedure code 82105)

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>155.0-155.2</td>
<td>186.9</td>
<td>198.82</td>
</tr>
<tr>
<td>183.0</td>
<td>197.7</td>
<td>V10.43</td>
</tr>
<tr>
<td>186.0</td>
<td>198.6</td>
<td>V10.47</td>
</tr>
</tbody>
</table>

#### Gonadotropin, Chorionic (hCG) (procedure codes 84702-84703)

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>181</td>
<td>186.9</td>
<td>V10.43</td>
</tr>
<tr>
<td>183.0</td>
<td>198.6</td>
<td>V10.47</td>
</tr>
<tr>
<td>186.0</td>
<td>198.82</td>
<td></td>
</tr>
</tbody>
</table>

#### CA 125 (procedure code 86304)

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>183.0</td>
<td>198.6</td>
<td>V10.47</td>
</tr>
</tbody>
</table>

#### CA 27.29 and CA 15-3 (procedure code 86300)

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>174.0-174.9</td>
<td>175.0-175.9</td>
<td>V10.3</td>
</tr>
</tbody>
</table>

#### Bladder Tumor Antigen (procedure code 86294)

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Value</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>188.0-188.9</td>
<td>V10.51</td>
<td></td>
</tr>
</tbody>
</table>

### Diagnoses that Support Medical Necessity

N/A

### ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

### Diagnoses that DO NOT Support Medical Necessity

N/A

### Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy. Testing performed for tumor markers by investigational methods that are not approved by the FDA are not covered by Medicare.

Routine screening services are not covered by Medicare.

All other tumor markers (e.g., procedure code 86316) including those listed below are considered investigational and therefore, ineligible for payment.

- A2-PAG
- BCM
- CA19-9
- CA50
- CA72-4
- CA195
- CA242
- CA549
- CA-SCC
- CAM17-1
- CAM26
- CAM29
- CAR3
- DU-PAN-2
- MCA
- NSE
- P-LAP
- PNA-ELLA
- SLEX
- SLX
- SPAN-1
- ST-439
- TAG12
- A2-PAG pregnancy-associated alpha2 glycoprotein
- BCM breast cancer mucin
- CA19-9 Cancer antigen 19-9 (procedure code 86301)
- CA50 Cancer antigen 50
- CA72-4 Cancer antigen 72-4
- CA195 Cancer antigen 195
- CA242 Cancer antigen 242
- CA549 Cancer antigen 549
- CA-SCC Squamous cell carcinoma
- CAM17-1 Monoclonal antimucin antibody 17-1
- CAM26 Monoclonal antimucin antibody 26
- CAM29 Monoclonal antimucin antibody 29
- CAR3 Antigenic determinant recognized by monoclonal antibody AR3
- DU-PAN-2 Sialylated carbohydrate antigen DU-PAN-2
- MCA Mucin-like carcinoma associated antigen
- NSE Neuron-specific enolase
- P-LAP Placental alkaline phosphatase
- PNA-ELLA Peanut lectin bonding assay
- SLEX Sialylated Lewis X-antigen
- SLX Sialylated SSEA-1 antigen
- SPAN-1 Sialylated carbonated antigen SPAN-1
- ST-439 Sialylated carbonated antigen ST-439
- TAG12 Tumor-associated glycoprotein 12
TAG72: Tumor-associated glycoprotein 72
TAG72.3: Tumor-associated glycoprotein 72.3
TATI: Tumor-associated trypsin inhibitor
TNF-a: Tumor necrosis factor alpha
TPA: Tissue polypeptide antigen

**Noncovered ICD-9-CM Code(s)**
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

**Noncovered Diagnoses**
N/A

**Coding Guidelines**
Claims for tumor antigen tests will be denied unless medical necessity is established by use of one or more of the above procedure and diagnosis codes.

When billing for a tumor antigen which is not FDA-approved or is considered investigational or experimental in nature, use code A9270 which represents a noncovered item or service.

**Documentation Requirements**
Medical record documentation maintained by the ordering/referring physician must indicate the medical necessity for performing this test, including the appropriate ICD-9-CM codes. This information is usually found in the history and physical, office/progress notes, and/or laboratory results.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the test results and interpretation, along with copies of the ordering/referring physician’s order for the studies. The physician must state the clinical indication/medical necessity for the study in his order for the test.

**Utilization Guidelines**
N/A

**Other Comments**
N/A

**Sources of Information**
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

**Advisory Committee Notes**
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

**Start Date of Comment Period**
N/A

**Start Date of Notice Period**
02/01/2001

**Revision History**
Revision Number: 3 PCR B2001-026
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

**Advance Notice Statement**
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

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**Medical Policy Procedures: 82108**

The LMRP for Aluminum (policy number 82108) was published in the July/August 2000 Medicare B Update! (pages 51-53). Since that time, the “ICD-9-CM Codes that Support Medical Necessity” section has been revised as follows:

### ICD-9-CM Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>268.2</td>
<td>Osteomalacia, unspecified</td>
</tr>
<tr>
<td>275.49</td>
<td>Other disorders of calcium metabolism</td>
</tr>
<tr>
<td>280.9</td>
<td>Iron deficiency anemia, unspecified [Microcytic (hypochromic) anemia]</td>
</tr>
<tr>
<td>284.8</td>
<td>Other specified aplastic anemias [Aplasia, bone marrow (secondary)]</td>
</tr>
<tr>
<td>284.9</td>
<td>Aplastic anemia, unspecified [Aplasia, bone marrow (myeloid or idiopathic)]</td>
</tr>
<tr>
<td>285.1</td>
<td>Acute posthemorrhagic anemia [Acute microcytic anemia]</td>
</tr>
<tr>
<td>294.8</td>
<td>Other specified organic brain syndromes (chronic) [(Encephalopathy] due to dialysis)</td>
</tr>
<tr>
<td>348.3</td>
<td>Encephalopathy, unspecified (acute)</td>
</tr>
<tr>
<td>359.4*</td>
<td>Toxic myopathy (due to drugs)</td>
</tr>
<tr>
<td>428.1</td>
<td>Left heart failure</td>
</tr>
<tr>
<td>429.3</td>
<td>Cardiomegaly</td>
</tr>
<tr>
<td>585</td>
<td>Chronic renal failure</td>
</tr>
<tr>
<td>733.10-733.19</td>
<td>Pathologic fracture</td>
</tr>
<tr>
<td>965.1</td>
<td>Poisoning by salicylates</td>
</tr>
<tr>
<td>972.2</td>
<td>Poisoning by antiinflammatory and antiarteriosclerotic drugs</td>
</tr>
<tr>
<td>973.0</td>
<td>Poisoning by antacids and antigastric secretion drugs</td>
</tr>
<tr>
<td>976.1</td>
<td>Poisoning by antipruritics</td>
</tr>
<tr>
<td>976.2</td>
<td>Poisoning by local astringents and local detergents</td>
</tr>
<tr>
<td>976.3</td>
<td>Poisoning by emollients, demulcients, and protectants</td>
</tr>
<tr>
<td>985.9</td>
<td>Toxic effect of unspecified metal (industrial exposure)</td>
</tr>
<tr>
<td>E858.3*</td>
<td>Accidental poisoning by agents primarily affecting cardiovascular system</td>
</tr>
<tr>
<td>E858.4*</td>
<td>Accidental poisoning by agents primarily affecting gastrointestinal system</td>
</tr>
<tr>
<td>E858.7*</td>
<td>Accidental poisoning by agents primarily affecting skin and mucous membrane, ophthalmological, otorhinolaryngological, and dental drugs</td>
</tr>
<tr>
<td>E935.3*</td>
<td>Drugs, medicinal and biological substances causing adverse effects in therapeutic use, salicylates</td>
</tr>
<tr>
<td>E942.2*</td>
<td>Drugs, medicinal and biological substances causing adverse effects in therapeutic use, antiinflammation and antiarteriosclerotic drugs</td>
</tr>
<tr>
<td>E943.0*</td>
<td>Drugs, medicinal and biological substances causing adverse effects in therapeutic use, antacids and antigastric secretion drugs</td>
</tr>
<tr>
<td>E946.2*</td>
<td>Drugs, medicinal and biological substances causing adverse effects in therapeutic use, local astringents and local detergents</td>
</tr>
<tr>
<td>E946.3*</td>
<td>Drugs, medicinal and biological substances causing adverse effects in therapeutic use, demulcients, protectants</td>
</tr>
</tbody>
</table>
Suicide and self-inflicted poisoning by analgesics, antipyretics, and antirheumatics

Suicide and self-inflicted poisoning by other specified drugs and medicinal substances

* These ICD-9 codes require dual diagnoses. ICD-9-CM code 359.4 must be accompanied by the appropriate E diagnosis code to identify the toxic agent. Conversely, the E diagnosis codes must be billed with ICD-9-CM code 359.4 to identify the indication of toxic myopathy.

All additional criteria listed in the policy continue to apply. For specific information, please refer to the “Indications and Limitations of Coverage and/or Medical Necessity”, “Coding Guidelines,” “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the July/August 2000 Update!

Medical Policy Procedures: 82435
Policy Number 82435
Contractor Name First Coast Service Options, Inc.
Contractor Number 00590
Contractor Type Carrier
LMRP Title Chloride
AMA CPT Copyright Statement CPT codes, descriptions, and other data only are copyright 2000 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.
HCFA National Coverage Policy Coverage Issues Manual, Section 50-17 Medicare Carriers Manual, Section 4270.2
Primary Geographic Jurisdiction Florida
Secondary Geographic Jurisdiction N/A
HCFA Region Region IV
HCFA Consortium Southern
Policy Effective Date 03/19/2001
Revision Effective Date N/A
Revision Ending Effective Date N/A
Policy Ending Date N/A
LMRP Description Chloride is an anion that exists primarily in the extracellular spaces as part of sodium chloride or hydrochloric acid. Chloride maintains cellular integrity through its influence on osmotic pressure and acid-base and water balance. Chloride concentration increases or decreases in response to concentrations of other anions.

Measurement of chloride is usually done for inferential value and is helpful in diagnosing disorders of acid-base and water balance. The normal adult serum chloride level is 96-106 mEq/L.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider a serum chloride test medically reasonable and necessary when performed for the following indications:

1. Evaluation of patients with signs and symptoms of hypochloremia. Signs and symptoms of hypochloremia include, but are not limited to, the following:
   - Hyperexcitability of the nervous system and muscles
   - Shallow breathing
   - Hypotension
   - Tetany

   Conditions in which serum chloride may be medically reasonable and necessary include, but are not limited to, the following which are related to hypochloremia:
   - Severe vomiting
   - Severe diarrhea
   - Excessive sweating
   - Gastric suction
   - Chronic respiratory acidosis
   - Burns
   - Metabolic alkalosis
   - Congestive heart failure
   - Addison’s disease
   - Primary aldosteronism
   - Syndrome of inappropriate antidiuretic hormone (SIADH)
   - Overhydration or water intoxication
   - Acute intermittent porphyria

2. Evaluation of patients with signs and symptoms of hyperchloremia. Signs and symptoms of hyperchloremia can include, but are not limited to, the following:
   - Lethargy
   - Weakness
   - Deep breathing

   Conditions in which serum chloride may be medically reasonable and necessary include, but are not limited to, the following which are related to hyperchloremia:
   - Dehydration
   - Cushing’s syndrome
   - Hyperventilation which causes respiratory alkalosis
   - Metabolic acidosis with prolonged diarrhea
   - Hyperparathyroidism
   - Renal tubular acidosis
   - Diabetes insipidus
   - Salicylate intoxication
   - Head injury with hypothalmic damage
   - Multiple myeloma
   - Acute or chronic renal failure
   - Excessive infusion of sodium chloride
   - Hyperchloremic acidosis resulting from gastrointestinal bicarbonate loss caused by drugs (e.g., calcium chloride, magnesium sulfate, and cholestyramine)
Hyperchloremic acidosis resulting from drug induced hyperkalemia with renal insufficiency (e.g., potassium sparing diuretics, trimethoprim, pentamidine, angiotensin-converting enzyme inhibitors, nonsteroidal anti-inflammatory drugs, and cyclosporine)

Even though a patient has a condition stated above, it is not expected that a serum chloride test be performed frequently for stable chronic symptoms that are associated with that disease.

Interpretation of chloride usually requires clinical information and other electrolytes such as sodium, potassium, and carbon dioxide to assess electrolyte, acid-base, and water balance.

In accordance with national Medicare coverage policy, serum chloride laboratory tests are routinely covered at a frequency of once per month for hemodialysis, intermittent peritoneal dialysis, continuous cycling peritoneal dialysis, and hemofiltration beneficiaries. Services performed at a greater frequency are covered if medically necessary and used in timely medical decision making.

HCPCS Section & Benefit Category
Pathology and Laboratory/Chemistry

CPT Codes
82435

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
203.00-203.01 276.0-276.9 585
252.0 277.1 588.8
253.5 428.0 780.79
253.6 518.81 780.8
255.0 518.83 781.7
255.1 518.84 786.01
255.4 536.2 965.1

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
Routine serum chloride laboratory tests, those performed at a frequency of once per month for hemodialysis, intermittent peritoneal dialysis, continuous cycling peritoneal dialysis, and hemofiltration beneficiaries, are included in the renal facility’s composite rate and may not be billed separately to the Medicare program. Serum chloride tests performed more frequently than once per month are separately billable if medically justified. A diagnosis of ESRD (ICD-9-CM code 585) alone is not sufficient medical evidence for coverage of additional tests.

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the test results and interpretation, along with the ordering physician’s order for the test. The physician must state the clinical indication/medical necessity for the study in his/her order for the test.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

Carrier Advisory Committee Meeting held on November 11, 2000.

Start Date of Comment Period
11/03/2000

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: Original PCR B2001- 065
Start Date of Comment Period: 11/03/2000
Start Date of Notice Period: 02/01/2001

Original Effective Date: 03/19/2001 Update!

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Medical Policy Procedures: 84152

Policy Number
84152

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Complexed and Free Prostate Specific Antigen

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HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
08/16/1999

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Prostate-specific antigen (PSA) is a serum glycoprotein tumor marker used in the early detection of prostate cancer. The PSA exists in multiple forms in serum and is predominantly complexed to protease inhibitors; however, one form of PSA, free PSA, is not bound to these proteins. The measurement of PSA forms in serum helps discriminate between prostate cancer and benign prostatic disease. For unknown reasons, the percentage of free PSA (fPSA) is lower in serum samples from patients with prostate cancer than in serum samples from patients with a normal prostate or benign disease.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider a complexed or free PSA medically reasonable and necessary in the following circumstances:

- To evaluate the patient whose total PSA level is between 4.0-10.0 ng/mL and has a palpable benign prostate gland; and
- To eliminate the need for unnecessary biopsies.

A complexed and free PSA are not indicated for patients that demonstrate a palpable abnormal gland that is suspicious for carcinoma. In addition, since this test is used to eliminate unnecessary biopsies, usually when the complexed or free PSA to total PSA ratio is at least 25%, it is not expected that a biopsy would be performed on patients with documentation suggestive of benign prostatic disease.

NOTE: Complexed and Free PSA are not medically necessary to monitor for the recurrence of disease or to monitor the response of therapy.

HCPCS Section & Benefit Category
Pathology and Laboratory/Chemistry

CPT Codes

- 84152 Prostate specific antigen (PSA); complexed (direct measurement)
- 84154 free

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
790.93

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Coding Guidelines
Since complexed and free PSA measure identical information, however, in a converse relationship, it is not expected that both a complexed PSA and a free PSA be performed when evaluating the patient for the conditions identified in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.
**Documentation Requirements**
Medical record documentation maintained by the ordering physician must clearly indicate the medical necessity of the services being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or test results.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician’s order for the studies. The physician must state the clinical indication/medical necessity for the study in his order for the test.

**Utilization Guidelines**
N/A

**Other Comments**
N/A

**Sources of Information**
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

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**Medical Policy Procedures: Psychiatric Partial Hospitalization Program**

**Policy Number**
PHPPROG

**Contractor Name**
First Coast Service Options, Inc.

**Contractor Number**
00590

**Contractor Type**
Carrier

**LMRP Title**
Psychiatric Partial Hospitalization Program

**AMA CPT Copyright Statement**
CPT codes, descriptions, and other data only are copyright 1998 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Apply.

**HCFA National Coverage Policy**
Title XVIII of the Social Security Act, Section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary.
Social Security Act, Section 1861 (ff) and 1832 (a). These sections define the partial hospitalization benefit and provide coverage of partial hospitalization in a hospital or CMHC setting.
The Social Security Act, Section 1861 (s) (2) (B). This section references partial hospitalization in a hospital outpatient setting.
The Social Security Act, Section 1835 (a). This section references physician certification.
The Social Security Act, Section 1833 (e). This requires services to be documented in order for payment to be made.
42 Code of Federal Regulations 410.2, 410.3, 410.43, 410.110, and 424(e)
Federal Register 2/11/94, (59 FR 6570)

**Advisory Committee Notes**
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives the Florida Urology Society.

**Start Date of Comment Period**
N/A

**Start Date of Notice Period**
02/01/2001

**Revision History**
Revision Number: 1  PCR B2001-029
Start Date of Comment Period:  N/A
Start Date of Notice Period:    02/01/2001
2nd Qtr 2001 Update!
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

**Advance Notice Statement**
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

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**Primary Geographic Jurisdiction**
Florida

**Secondary Geographic Jurisdiction**
N/A

**HCFA Region**
Region IV

**HCFA Consortium**
Southern

**Policy Effective Date**
06/19/2000

**Revision Effective Date**
01/01/2001

**Revision Ending Effective Date**
12/31/2000

**Policy Ending Date**
N/A

**LMRP Description**
Individuals requiring psychiatric care generally receive services along a continuum of care which involves three levels - inpatient, partial hospitalization, and outpatient.
Partial hospitalization services provided in a CMHC require general supervision and oversight of the program by a physician (MD/DO). General supervision means the physician must at least be available by telephone.

Patients eligible for Medicare reimbursement for PHP services are:

- Those patients who are directly discharged or transitioned from an inpatient hospital treatment program and the PHP admission is in lieu of continued inpatient treatment.
- Those patients who, in the absence of the partial hospitalization, would require inpatient hospitalization. It is generally expected that less intensive treatment in an outpatient setting be attempted prior to admission to partial hospitalization. Documentation for such patients should support these attempts, as well as the patient’s failure at or inability to be managed in a less intensive outpatient setting.

The following eligibility requirements must also be met:

- The services must be reasonable and necessary for the diagnosis or active treatment of the individual’s condition.
- The patient must be under the care of a physician (M.D./D.O.) trained in the diagnosis and treatment of psychiatric illness, who is knowledgeable about the patient and certifies the need for partial hospitalization.
- The patient or legal guardian must provide written informed consent for partial hospitalization treatment.
- The patient must require comprehensive, multimodal treatment requiring medical supervision and coordination because of a mental disorder, which severely interferes with multiple areas of daily life including social, vocational, and/or educational functioning. Such dysfunction must be an acute illness or exacerbation of a chronic illness (acute in nature).
- The patient must have the capacity for active participation in all phases of the multidisciplinary and multimodal program (i.e., the patient is medically stable and not limited by another serious medical condition, the patient demonstrates an appropriate level of cognition).
- There must be reasonable expectation of improvement in the patient’s disorder and level of functioning as a result of the active treatment provided by the PHP.
- The active treatment must directly address the presenting problems necessitating admission to the PHP and be vigorous and proactive as opposed to passive and custodial. Active treatment consists of clinically recognized therapeutic interventions including individual, group, and family psychotherapies, occupational, activity, and psychoeducational groups pertinent to the patient’s current illness. Medical and psychiatric diagnostic evaluation and medical management are also integral to active treatment. Evidence of active monitoring of the patient’s physical status, which could impact the patient’s psychiatric condition, is required.
- The individualized treatment plan is developed by a physician and the multidisciplinary team, with the patient’s involvement.
- A physician must provide supervision and evaluation of the patient’s treatment and the extent to which the therapeutic goals are being met.
- The program must be prepared to appropriately treat...
the co-morbid substance abuse disorder when it exists (dual diagnosis patients). Dual diagnosed individuals suffer from concomitant mental illness and chemical dependency. Sobriety, as an initial clinical goal, is essential for further differential diagnosis and clinical decisions about appropriate treatment. It is not generally expected that a patient who is actively using a chemical substance be admitted to or engaged in a partial hospitalization program, as a patient under the influence of a chemical substance would not be capable of actively participating in his/her psychiatric treatment program.

Admission Criteria (Intensity of Service)
In general, patients should be treated in the least intensive and restrictive setting which meets the needs of their illness.

Patients admitted to a PHP must:

- **Not require a 24-hour a day level of care as provided in an inpatient setting.** Therefore, it is not expected for the patient to be an inpatient.

- **Have an adequate support system to sustain/maintain themselves outside the partial program.** The patient is expected to have an identifiable significant support system while he/she is not actively engaged in the program (i.e., in the evening, on the weekend, or anytime the PHP services are not available).

- **Require PHP services at a level of intensity and frequency comparable to patients in an inpatient setting for similar psychiatric illnesses.**

Admission Criteria (Severity of Illness)
Patients admitted to a PHP must:

- **Have an acute onset or decompensation of a covered Axis I mental disorder,** as defined by the Diagnostic and Statistical Manual, Fourth Edition (DSM-IV) published by the American Psychiatric Association (1994), which severely interferes with multiple areas of daily life.

- **Demonstrate a degree of impairment severe enough that without care or treatment, the person is likely to suffer from neglect or refusal to care for him or herself and such neglect or refusal poses a real and present threat of substantial harm** to his or her well being. This degree of impairment requires a multidisciplinary structured program, but is not so severe that the patient is incapable of participating in and benefiting from an active treatment program and be maintained outside the program.

- **Not be an immediate/imminent danger to self, others, or property.** There may be a **recent history of self-mutilation, serious risk taking, or other self-endangering behavior.** Evidence of appropriate safety measures should be in place to accommodate at-risk patients (e.g., a no harm contract with a specified emergency plan signed by the patient upon admission and re-affirmed upon the end of each treatment day).

Discharge Criteria (Intensity of Service):
Patients are appropriate for discharge from a partial hospitalization program, based on intensity of service, when:

- **The patient requires stepping up to an inpatient level of care.** The inpatient psychiatric admission (24 hour supervision) becomes necessary when the probability for self-harm, or harm to others exists.

- **The patient requires stepping down to a less intensive level of outpatient care.** Stepping down to a less intensive level of service than a partial hospitalization would be considered when the patient no longer requires the multidisciplinary or multimodal program.

If transitioning is required prior to discharge from the partial hospitalization program, the medical need for transitioning should be documented in the treatment plan.

In the **rare circumstance** of inability or failure to transition to a less intensive level, medical records must substantiate the need for a continuation in the PHP.

Discharge Criteria (Severity of Illness):
Patients are appropriate for discharge from a PHP, based on severity of illness, when:

- The patient’s clinical condition declines and the individual requires inpatient psychiatric care (24-hour supervision).

- The patient’s clinical condition improves or stabilizes and the individual no longer benefits from or requires the intensive, multimodal treatment of the PHP. This would be evidenced by a reduced impairment in daily functioning, symptom reduction, improved capacity to access community supports, accomplishment of treatment goals to extent possible, and ability to return to increased levels of independence in day-to-day activities.

Covered Services:
- Medically necessary diagnostic services related to mental health treatment.

- Individual or group psychotherapy rendered by physicians (MD/DO), psychologists, or other mental health professionals licensed or authorized by Florida State law (e.g., licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors).

** Professional services furnished by physicians, physician assistants, nurse practitioners, and clinical psychologists to patients in PHPs must be billed to the carrier.

- Occupational therapy, requiring the skills of an occupational therapist (OT), which is a component of the physician’s treatment plan for the patient. The occupational therapy services must be individualized and essential for the treatment of the patient’s diagnosed condition and for progress toward treatment goals. The physician’s treatment plan must clearly justify the need for each occupational therapy service modality utilized, and explain how it fits into the treatment of the patient’s mental illness and functional deficits. **Providers must not bill occupational therapy services as individual or group psychotherapy services.

- Services of other staff (social workers, psychiatric nurses and others) trained to work with psychiatric patients.

- Drugs and biologicals that cannot be self-administered and are furnished for psychotherapeutic purposes. **The medication must be safe and effective, and approved by the Food and Drug Administration. It cannot be experimental or administered under investigational protocol.**
• Individualized activity therapy that is not primarily recreational or diversionary. The activity therapy group must be individualized and essential for the treatment of the patient’s diagnosed psychiatric condition and for progress toward treatment goals. The physician’s treatment plan must carefully justify the need for each activity therapy modality utilized and explain how it fits into the treatment of the patient’s illness and functional deficits. Providers must not bill activity therapies as individual or group psychotherapy services.

• Family counseling services for which the primary purpose is the treatment of the patient’s condition. Such services include the need to observe the patient’s interaction with the family for diagnostic purposes, or to assess the capability of and assist the family members in aiding in the management of the patient.

• Patient training and education, when the training and educational sessions are closely and clearly related to the individual’s care and treatment of their diagnosed psychiatric condition. Providers must not bill training and education as individual or group psychotherapy services. Providers must also not bill for general education (e.g., providing information in a group setting regarding a medication the patient is not receiving, information regarding the PHP’s schedule, policies, changes in personnel, etc.).

HCPCS Section & Benefit Category
Medicine, Psychiatry, Central Nervous System Assessments/Tests, Physical Medicine and Rehabilitation

CPT/HCPCS Codes
There are no specific CPT or HCPCS codes for partial hospitalization “programs”. However, outpatient hospitals are required to report the following appropriate codes for the individual or specific partial hospitalization services provided. Effective for dates of services on or after June 5, 2000, Community Mental Health Centers are also required to utilize the same codes for reporting partial hospitalization services.

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There are codes on this list that may not be reimbursable through Medicare due to existing national or Local Medical Review Policies. Please refer to the applicable Medicare manuals and Local Medical Review Policies for coverage criteria information regarding each service.

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Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
A diagnosis that falls within the range of ICD-9-CM codes for mental illness (290.0-319). The diagnosis itself is not the sole determining factor for coverage.

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
• Services furnished by a facility other than an outpatient hospital or a community mental health center (CMHC);
• The treatment of chronic conditions without acute exacerbation;
• Individual or group psychotherapy rendered by someone who is not licensed or authorized by Florida State Law;
• Professional services of physicians, physician assistants, nurse practitioners, and clinical psychologists billed to the Intermediary;
• Occupational therapy services related primarily to specific employment opportunities, work skills, or work settings;
• Activity therapy that is primarily recreational or diversionary;
• Any service that does not have a specific treatment goal;
• Daycare programs, which provide primarily social, recreational, or diversion activities, custodial or respite care;
• Psychosocial programs attempting to maintain psychiatric wellness (e.g., daycare programs for the chronically mentally ill which provide only a structured environment, socialization, and/or vocational rehabilitation);
• Patients who are otherwise psychiatrically stable or require medication management only.
• Services to a skilled nursing facility or nursing home resident that should be expected to be provided by the nursing facility staff (e.g., adjustment difficulties related to their placement in the skilled nursing facility or nursing home);
• Services to hospital inpatients;
• Meals;
• Transportation;
• Self-administered medications;
• Vocational training;
• General education (e.g., information provided about the partial hospitalization program’s schedule, policies, changes in staffing, etc.);
• Biofeedback therapy for ordinary muscle tension or psychosomatic conditions;
• Transcendental meditation; and
• Electroconvulsive therapy (ECT).

Beneficiaries ineligible for partial hospitalization services:
• Patients who do not meet admission criteria for partial hospitalization services;
• Patients who cannot or refuse to participate (due to their behavioral, cognitive or emotional status) with the active treatment of their mental disorder, or who cannot tolerate the intensity of a partial hospitalization program;
LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

• Patients who require 24 hour supervision inpatient hospitalization because of the severity of their mental disorder or their safety or security risk;
• Patients who require primarily social, recreational, custodial, or respite care;
• Patients with multiple unexcused absences or who are persistently non-compliant;
• Individuals with an organic brain disorder (e.g., Dementia, Delirium, Alzheimer’s), or other psychiatric or neurologic conditions (Severe Head Trauma) which have produced a severe enough cognitive deficit to prevent establishment of a relationship with the therapist or other group members, or participation in insight oriented processes; and
• Patients who have met the criteria for discharge from the partial hospitalization program to a less intensive level of outpatient care.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines

Bundling Issues
The professional services (listed below) provided in a CMHC or hospital outpatient department are separately covered and paid as the professional services of physicians and independent practitioners. These direct professional services are “unbundled” and these practitioners (other than physician assistants, [PAs]), may bill the Medicare Part B carrier directly for the professional services furnished to hospital outpatient PHP patients and CMHC partial hospitalization patients. The hospital or CMHC can also serve as a billing agent for these professionals, by billing the Part B carrier on their behalf for their professional services (via the HCFA-1500 billing format). The professional services of a PA can be billed to the carrier only by the PA’s employer. The following direct professional services are unbundled and not paid as partial hospitalization services:

• Physician services that meet the criteria for payment on a fee schedule basis (in accordance with 42 CFR 414);
• Physician assistant services (as defined in section 1861(s)(2)(K)(I) of the Act);
• Clinical psychologist services (as defined in section 1861(ii) of the Act); and
• Advanced Registered Nurse Practitioners and Clinical Nurse Specialists (as defined in section 1861(s)(2)(K)(ii) of the Act).

The services of other practitioners, including licensed clinical social workers (LCSWs), are bundled when furnished under the PHP benefit. These bundled services are billed to the Medicare Part A intermediary via the HCFA-1450 (UB-92) billing format, and payment is made on a reasonable cost basis. Administrative (rather than professional) services remain bundled. The distinction between professional and administrative services is whether the services are directly furnished to an individual patient or are performed indirectly under the partial hospitalization program (outpatient hospital or CMHC). Currently, reimbursement for administrative services is made via the provider’s cost report settlement.

Therefore, administrative services are not separately billable to either the Part A intermediary (via the HCFA-1450) or the Part B carrier (via the HCFA-1500). In addition, effective August 1, 2000, payment for partial hospitalization programs will be made under the hospital outpatient prospective payment system.

• Outpatient Mental Health Treatment Limitation
The outpatient mental health treatment limitation may apply to services to treat mental, psychoneurotic, and personality disorders when furnished by physicians, clinical psychologists, NPs, CNSs, and PAs to partial hospitalization patients.

Documentation Requirements
The following documentation must be maintained in the patient’s medical record:

PHYSICIAN CERTIFICATION- The physician certification must be signed by a physician who is treating the patient and has knowledge of the patient’s response to treatment. A physician trained in the diagnosis and treatment of psychiatric illness must certify that the patient being admitted to the partial hospitalization program would require inpatient psychiatric hospitalization if the partial hospitalization services are not provided. It is generally expected that the physician certification will be completed within 24 hours of the patient’s admission to the partial hospitalization program.

PHYSICIAN RECERTIFICATION- The first recertification is required as of the 18th calendar day following admission to the PHP. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days. Recertification should be based on a thorough re-evaluation of the treatment plan in relation to the reason for admission and the progress of the patient.

Certifications may use any format desired and may be part of the treatment plan. However, the following statement must be used.

Certification Language:
“I certify that the patient would require Inpatient psychiatric care if the Partial Hospitalization services were not provided, and services will be furnished under the care of a physician, and under a written Plan of Treatment.”

Physician signature: _____________________________
Date: __________________

Recertification Language:
“I certify that continued Partial Hospitalization services are medically necessary to improve and/or maintain (circle one) the patient’s condition and functional level and to prevent relapse or hospitalization.”

Physician signature: _____________________________
Date: __________________

Certifications are prospective; the physician (M.D./D.O.) certifies that future services are required. A physician certification must cover all periods of service. Stamped signatures are not acceptable. A physician certification is required, but does not guarantee approval of services.

A psychologist is not considered a physician for the purpose of establishing a certification or recertification.
INITIAL PSYCHIATRIC EVALUATION- The initial psychiatric evaluation with medical history and physical examination must be performed and placed in the chart generally within 24 hours of admission in order to establish the medical necessity for partial hospitalization services. If the patient is being directly discharged from an inpatient psychiatric admission to a partial hospitalization program, an appropriate update to the inpatient psychiatric evaluation and medical history and physical is acceptable, as long as it is reflective of the patient’s condition upon admission to the PHP.

The initial evaluation should include the following documentation to support the medical necessity of the admission:

- Referral source;
- History of substance abuse including the type of substance used, frequency, amount and duration as well as symptoms of withdrawal or other complications (e.g., hepatitis or AIDS resulting from the use of contaminated needles);
- Family, vocational, and social history, including documentation of an adequate support system to sustain/maintain the patient outside the partial hospitalization program;
- Mental status examination, including general appearance and behavior, orientation, affect, motor activity, thought content, long and short term memory, estimate of intelligence, capacity for self harm or harm to others, insight, judgment, and capacity for activities of daily living (ADLs) with examples of specifics in each category and the method of elicitation when applicable;
- Physical examination (if not done within the past 30 days and/or not available from another provider for inclusion in the medical record);
- Formulation of the patient’s status, including an assessment of the reasonable expectation that the patient will make timely and significant practical improvement in the presenting acute symptoms, as a result of the active treatment provided by the partial hospitalization program;
- ICD-9/DSM-IV diagnoses, including all five axes of the multiaxial assessment as described in DSM-IV, to assist in establishing the patient’s baseline functioning;
- An initial treatment plan, including long and short term goals related to the active treatment of the reason for admission and the specific types, amount, duration, and frequency of therapy services required to address the goals; and
- Certification by the physician that the course of the patient’s current episode of illness would result in psychiatric inpatient hospitalization if the partial hospitalization services are not initiated at this time.

TREATMENT PLAN- An individualized formal treatment plan must be signed and dated by a physician and established within 7 days of admission to the program. NO STamped SIGNATURES WILL BE ACCEPTED.

The treatment plan must include the following:

- Physical examination (if not done within the past 30 days and/or not available from another provider for inclusion in the medical record);
- Formulation of the patient’s status, including an assessment of the reasonable expectation that the patient will make timely and significant practical improvement in the presenting acute symptoms, as a result of the active treatment provided by the partial hospitalization program; and
- ICD-9/DSM-IV diagnoses, including all five axes of the multiaxial assessment as described in DSM-IV, to assist in establishing the patient’s baseline functioning.

The frequency of treatment plan updates is always contingent upon an individual patient’s needs. The treatment planning updates must be based on the physician’s periodic consultation with therapists and staff, review of medical records, and patient interviews.

PROGRESS NOTES- A separate progress note must be written for each HCPCS or revenue code billed. The progress note must be legible, dated and signed, and include the credentials of the rendering provider.

The progress note must be written by the team member rendering the service and must include the following:

- The type of service rendered (name of the specific psychotherapy group, educational group, etc. if applicable);
- The problem/functional deficit to be addressed during the session, and how it relates to the patient’s current condition, diagnosis, and problem/deficit identified in the treatment plan;
- The content of the therapeutic session, as well as a clear description of the intervention used to assist the patient in reaching the related treatment goal;
- The patient’s status (behavior, verbalizations, mental status) during the session; and
- The patient’s response to the therapeutic intervention including benefit from the session and how it relates to progress made toward the short/long term goal in measurable and functional terms. Functional improvement is considered to be the patient’s increasing ability to function outside of the direction or support of a therapist and or therapeutic environment. Measures of functional improvement may include, but are not limited to, patient appearance, patient participation in therapy, or the patient’s performance of activities of daily living.

PHYSICIAN SUPERVISION AND EVALUATION-

Evidence must be documented in the patient’s medical record that a physician has provided direct patient care, provided supervision and direction to the therapist(s) and staff, reviewed the medical record, and determined the extent to which the therapeutic goals are being met.

ITEMIZED STATEMENT- An itemized statement must be maintained which identifies the date, HCPCS code, revenue code, and charge for each individual service rendered.

Utilization Guidelines

N/A

Other Comments

Psychotherapy is the treatment of mental illness and behavior disturbances, in which definitive therapeutic communication attempts to alleviate the emotional disturbances, reverse or change the maladaptive patterns of behavior and encourage personality growth and behavior.
**LOCAL AND FOCUSED MEDICAL REVIEW POLICIES**

**Sources of Information**
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

**Advisory Committee Notes**
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Psychiatric Society.

**Start Date of Comment Period**
N/A

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**Medical Policy Procedures: 93000**

**Policy Number**
93000

**Contractor Name**
First Coast Service Options, Inc.

**Contractor Number**
00590

**Contractor Type**
Carrier

**LMRP Title**
Electrocardiography

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**HCFA National Coverage Policy**
Coverage Issues Manual, Section 50-15

**Primary Geographic Jurisdiction**
Florida

**Secondary Geographic Jurisdiction**
N/A

**HCFA Region**
Region IV

**HCFA Consortium**
Southern

**Policy Effective Date**
08/19/1996

**Revision Effective Date**
11/21/2000

**Revision Ending Effective Date**
11/20/2000

**Policy Ending Date**
N/A

**LMRP Description**
Electrocardiography (ECG, EKG) is the graphic tracing of the variations in electrical potential caused by the excitation of the heart muscle as detected at the body surface by electrodes placed on the patient’s limbs and chest. The monitoring electrodes detect the electrical activity of the heart from a variety of spatial perspectives. The EKG lead system is composed of several electrodes that are placed on each of the four extremities and at varying sites on the chest. It provides information regarding rate, rhythm, myocardial injury, and conduction system.

The normal EKG pattern is composed of waves arbitrarily designated by the letters P, Q, R, S, and T. Through the analysis of these wave forms and time intervals, valuable information about the heart may be obtained. The EKG is used primarily to identify abnormal heart rhythms (arrhythmias or dysrhythmias) and to diagnose acute myocardial defects, ventricular hypertrophy, and/or strain.

**Indications and Limitations of Coverage and/or Medical Necessity**
Electrocardiograms are indicated for diagnosis and patient management purposes involving symptoms of the heart, pericardium, thoracic cavity, and system diseases which produce cardiac abnormalities.

Florida Medicare will consider an EKG medically necessary in any of the following circumstances:

1. Initial diagnostic workup for a patient that presents with complaints of symptoms such as chest pain, palpitations, dyspnea, dizziness, syncope, etc. which may suggest a cardiac origin.
2. Evaluation of a patient on a cardiac medication for a cardiac arrhythmia or other cardiac condition which affects the electrical conduction system of the heart (e.g., inotropics such as digoxin; antiarrhythmics such as Tambocor, Procainamide, or Quinidine; and antianginals such as Cardizem, Isordil, Corgard, Procardia, Inderal and Verapamil). The EKG is necessary to evaluate the effect of the cardiac medication on the patient’s cardiac rhythm and/or conduction system.
3. Evaluation of a patient with a pacemaker with or without clinical findings (history or physical examination) that suggest possible pacemaker malfunction.
4. Evaluation of a patient who has a significant cardiac arrhythmia or conduction disorder in which an EKG is necessary as part of the evaluation and management of...
the patient. These disorders may include, but are not limited to, the following: Complete Heart Block, Second Degree AV Block, Left Bundle Branch Block, Right Bundle Branch Block, Paroxysmal VT, Atrial Fib/Flutter, Ventricular Fib/Flutter, Cardiac Arrest, Frequent PVCs, Frequent PACs, Wandering Atrial Pacemaker, and any other unspecified cardiac arrhythmia.

5. Evaluation of a patient with known Coronary Artery Disease (CAD) and/or heart muscle disease that presents with symptoms such as increasing shortness of breath (SOB), palpitations, angina, etc.

6. Evaluation of a patient’s response to a newly established therapy for angina, palpitations, arrhythmias, SOB or other cardiopulmonary disease process.

7. Evaluation of patients after coronary artery revascularization by Coronary Artery Bypass Grafting (CABGs), Percutaneous Transluminal Coronary Angiography (PTCA), thrombolytic therapy (e.g., TPA, Streptokinase, Urokinase), and/or stent placement.

8. Evaluation of patients presenting with symptoms of a Myocardial Infarction (MI).

9. Evaluation of other symptomatology which may indicate a cardiac origin especially in those patients who have a history of an MI, CABG surgery or PTCA or patients who are being treated medically after a positive stress test or cardiac catheterization.

10. Pre-operative Evaluation of the patient when:
   - undergoing cardiac surgery such as CABGs, automatic implantable cardiac defibrillator, or pacemaker, or
   - the patient has a medical condition associated with a significant risk of serious cardiac arrhythmia and/or myocardial ischemia such as Dressler’s Syndrome, history of MI, angina pectoris, aneurysm of heart wall, chronic ischemic heart disease, pericarditis, valvular disease or cardiomyopathy to name a few.

11. Evaluation of a patient’s response to the administration of an agent known to result in cardiac or EKG abnormalities (for patients with suspected, or at increased risk of developing, cardiovascular disease or dysfunction). Examples of these agents are antineoplastic drugs, lithium, tranquilizers, anticonvulsants, and antidepressant agents.

Note: An EKG performed as a baseline evaluation prior to the initiation of an agent known to result in cardiac or EKG abnormalities is considered screening and is noncovered by Medicare.

ICD-9-CM Codes that Support Medical Necessity

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Diagnoses that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses

N/A

Coding Guidelines

When using diagnosis code V72.81, it is expected that the medical record would contain information supporting either of the two pre-operative evaluation indications listed under the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

If an EKG is being performed to evaluate a patient’s response to the administration of an agent known to result in cardiac or EKG abnormalities for patients with suspected, or at increased risk of developing cardiovascular disease or dysfunction, then diagnosis code V58.69 or V58.83 should be used. The “E” diagnoses should be used when the patient is experiencing adverse effects to high risk medications.

Documentation Requirements

Medical record documentation (e.g., office/progress notes) maintained by the ordering/referring physician must indicate the medical necessity for performing the test. Additionally, the EKG strip and a copy of the test results should be maintained in the medical record.
If the provider of service is other than the ordering/referring physician, that provider must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician’s order for the studies. The physician must state the clinical indication/medical necessity for the study in his order for the test.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Chapter of the American College of Cardiology.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 10  PCR B2000-172
Start Date of Comment Period:  N/A
Start Date of Notice Period:  02/01/2001
2nd Qtr 2001 Update!
Revised Effective Date:  11/21/2000
Explanation of Revision:  Based on an inquiry, additional diagnoses were added to use when an EKG is performed to monitor patients taking high risk medications that cause cardiac or EKG abnormalities.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.

MLRM Description
Transesophageal Echocardiography (TEE) is a cardiac diagnostic procedure in which a modified endoscope, with an ultrasound transducer, is passed into the esophagus and/or stomach in order to obtain 2-D echo images and spectral and color doppler information about the heart and its great vessels.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider transesophageal echocardiogram to be medically necessary in any of the following circumstances (see Covered ICD-9-CM Codes):

- Examination of prosthetic heart valves, primarily mitral
- Detection of:
  - aortic dissection
  - atrial septal defect
  - congenital heart disease
  - embolism or thrombosis, primarily involving left atrium
  - intracardiac foreign bodies, tumors or masses
  - mitral valve regurgitation
  - vegetative endocarditis
- Intra-operative guide to left ventricular function
- Inadequacy of transthoracic echo due to:
  - chest wall deformity, COPD
  - open heart or chest surgery
  - chest trauma
  - obesity

MLRM Title
Transesophageal Echocardiogram

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HCFA National Coverage Policy
Coverage Issues Manual, Section 50-7
Medicare Carriers Manual, Section 2070

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
10/16/1995

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000
### HCPCS Section & Benefit Category
Medicine/Cardiovascular

### CPT Codes
- 93312
- 93313
- 93314
- 93316
- 93318
- 93319
- 93317

### Not Otherwise Classified Codes (NOC)
N/A

### ICD-9-CM Codes that Support Medical Necessity

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<th>Code</th>
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<td>212.7</td>
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### Diagnoses that Support Medical Necessity
N/A

### ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

### Diagnoses that DO NOT Support Medical Necessity
N/A

### Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

### Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

### Noncovered Diagnoses
N/A

### Coding Guidelines
If the service of the cardiologist is requested for a specific reason, his professional services would be billed with CPT 93314 or 93317 with the 26 modifier.

### Documentation Requirements
Medical record documentation maintained by the ordering/referring physician must clearly indicate the medical necessity of transesophageal echocardiography studies covered by the Medicare program. Also, the results of transesophageal echocardiography studies covered by the Medicare Program must be included in the patient’s medical record.

If the provider of transesophageal echocardiography studies is other than the ordering/referring physician, the provider of the service must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician’s order for the studies. When ordering transesophageal echocardiography studies, the ordering/referring physician must state the reason for the study in his order.

### Utilization Guidelines
N/A

### Other Comments
N/A

### Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

### Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from Anesthesiology and Cardiology Societies.

### Start Date of Comment Period
N/A

### Start Date of Notice Period
02/01/2001

### Revision History
- **Revision Number:** 5  
  **PCR B2001-037**  
  **Start Date of Comment Period:** N/A  
  **Start Date of Notice Period:** 02/01/2001  
  **Revised Effective Date:** 01/01/2001  
  **Advance Notice Statement:** 2nd Qtr 2001 Update!  
  **Advance Notice Statement:** Annual 2001 HCPCS update

### Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Medical Policy Procedures: 93619

Policy Number
93619

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Intracardiac Electrophysiological Evaluation

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HCFA National Coverage Policy
Coverage Issues Manual, Section 35-85

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
10/01/1993

Revision Effective Date
03/19/2001

Revision Ending Effective Date
03/18/2001

Policy Ending Date
N/A

LMRP Description
An intracardiac electrophysiological evaluation is a study of the electrical processes involved with the heart action.

Indications and Limitations of Coverage and/or Medical Necessity
Electrophysiological Evaluation [procedure codes 93619, 93620-93624, 93631] :
Electrophysiological studies routinely require vascular access, injections/infusions, and continuous monitoring. In the course of an electrophysiological study, an advanced pacing device is routinely used to stimulate and record intracardiac activities.

Electrophysiological Evaluation of Cardioverter-Defibrillator [procedure code 93640-93642] :
Effective for services performed on or after January 24, 1986 through July 01, 1991, electrophysiologic evaluation of cardioverter-defibrillator and/or leads (93640, 93641, 93642) is covered only when the automatic defibrillator was implanted into a patient who had one of the following indications:

1. A documented episode of life threatening ventricular tachyarrhythmia; or
2. Cardiac arrest not associated with myocardial infarction.

These patients must have been found, by electrophysiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy).

Effective for services performed on or after July 01, 1991, electrophysiologic evaluation of cardioverter-defibrillator is a covered service if the automatic defibrillator was implanted into a patient who had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction.

Effective for services performed on or after July 01, 1999, electrophysiologic evaluation of cardioverter-defibrillator is a covered service if the automatic defibrillator was implanted into a patient who had any of the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or,
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

In addition to the above coverage indications, procedure codes 93642 is covered to periodically follow-up or evaluate a patient’s cardioverter-defibrillator status.

HCPCS Section & Benefit Category
Medicine/Cardiovascular

CPT Codes
93619
93620
93621
93622
93623
93624
93631
93640
93641
93642

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

For procedure codes 93619, 93620-93624, 93631:
426.0  426.9  427.61
426.10-426.13  427.0  427.69
426.2  427.1  427.81
426.3  427.2  427.89
426.4  427.31-427.32  427.9
426.50-426.54  427.41-427.42  746.9
426.6  427.5  780.2
426.7

For procedure codes 93640 – 93642:
425.1  427.5  996.04
425.4  794.31  V45.02
427.1

Diagnoses that Support Medical Necessity
N/A
ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
N/A

Documentation Requirements
Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the services being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedural report.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information
N/A

Advisory Committee Notes
N/A

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 6
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

Revised Effective Date: 03/19/2001
Explanation of Revision: The electronic analysis of a cardioverter-defibrillator is included in another policy titled “Electronic Analysis of Pacemaker System and Pacer Cardioverter-Defibrillator”, therefore, the procedure codes 93737 and 93738 were deleted from this policy.

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Indications and Limitations of Coverage and/or Medical Necessity

Electronic analysis to monitor the patient’s pacemaker and/or cardioverter-defibrillator is medically necessary on a regular basis to evaluate the device. The frequency of follow-up is determined by the patient’s attending physician who takes into account the condition and circumstances of the individual patient. If the monitoring is done by some entity other than the patient’s physician, such as a commercial monitoring service or hospital outpatient department, the physician’s prescription for monitoring is required and must be renewed at least annually to assure that the frequency of monitoring is proper for the patient. When services are performed by entities other than the attending physician, such as monitoring services and pacemaker clinics, it is expected that the information obtained from these monitoring activities be communicated to the attending physician for use in the management of the patient’s condition. This information must be documented in the patient’s medical record.

Transtelephonic Monitoring of Cardiac Pacemakers (procedure codes 93733 and 93736)

Telephone monitoring of pacemakers is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement. All systems which monitor the pacemaker rate (bpm) in both the free-running and/or magnetic mode are effective in detecting subclinical pacemaker failure due to battery depletion. More sophisticated systems are also capable of detecting internal electronic problems within the pulse generator itself and other potential problems. In the case of dual chamber pacemakers, such monitoring may detect failure of synchronization of atria and ventricles, and the need for adjustment and reprogramming of the device.

In order for transtelephonic monitoring services to be covered, the services must consist of the following elements:

- A minimum 30-second readable strip of the pacemaker in the free-running mode;
- Unless contraindicated, a minimum 30-second readable strip of the pacemaker in the magnetic mode; and
- A minimum 30 seconds of readable ECG strip.

National Medicare Frequency Guidelines

Frequency guidelines for transtelephonic monitoring (procedure codes 93733 and 93736) are divided into two categories: Guideline I which applies to the majority of pacemakers now in use and Guideline II which applies to pacemaker systems for which sufficient long-term clinical information exists to assure that they meet the standards of the Intersociety Commission for Heart Disease Resources (ICHD) for longevity and end-of-life decay. The two groups of guidelines are further divided into single and dual-chamber pacemakers. The frequency guidelines identified below represent the maximum frequency of transtelephonic monitoring that is expected to occur under routine follow-up. The frequency with which a patient is monitored may be changed for a number of reasons, such as a change in the patient’s overall condition, a reprogramming of the patient’s pacemaker, and the development of better information on the pacemaker’s longevity or failure mode.

**Guideline I**

<table>
<thead>
<tr>
<th>Single-chamber pacemaker</th>
<th>Dual-chamber pacemaker</th>
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<tbody>
<tr>
<td>1st month – every 2 weeks</td>
<td>1st month – every 2 weeks</td>
</tr>
<tr>
<td>2nd through 36th month – every 8 weeks</td>
<td>2nd through 48th month – every 12 weeks</td>
</tr>
<tr>
<td>37th month to failure – every 4 weeks</td>
<td>49th through 72nd month – every 8 weeks</td>
</tr>
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</table>

**Guideline II**

<table>
<thead>
<tr>
<th>Single-chamber pacemaker</th>
<th>Dual-chamber pacemaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st month – every 2 weeks</td>
<td>1st month – every 2 weeks</td>
</tr>
<tr>
<td>2nd through 6th month – every 4 weeks</td>
<td>2nd through 8th month – every 12 weeks</td>
</tr>
<tr>
<td>7th through 36th month – every 8 weeks</td>
<td>31st through 48th month – every 8 weeks</td>
</tr>
<tr>
<td>37th month to failure – every 4 weeks</td>
<td></td>
</tr>
</tbody>
</table>

Pacemaker Clinic Services

Pacemaker monitoring (procedure codes 93724, 93731-93732, 93734-93735) is covered by pacemaker clinics and may be done in conjunction with transtelephonic monitoring or as a separate service. The services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers.

The frequency of pacemaker clinic services is the decision of the patient’s physician, taking into account the medical condition of the patient. The following monitoring guidelines apply to lithium-battery pacemakers (all pacemakers currently have lithium batteries):

- Single-chamber pacemakers – twice in the first 6 months following implant, then once every 12 months.
- Dual-chamber pacemakers – twice in the first 6 months, then once every 6 months.

Local Medicare Frequency Guidelines

Electronic analysis of a pacing cardioverter-defibrillator (procedure codes 93737-93744) is performed in an office or outpatient hospital setting. Procedure codes 93737-93738 include only interrogation and evaluation of the pulse generator status without any attempt made to induce an arrhythmia or to evaluate defibrillation thresholds. Procedure codes 93741-93744 involve the interrogation and evaluation of the pulse generator status in addition to evaluation of the programmable parameters, analysis of event markers and device response during periods of rest and activity. The monitoring of these complex devices requires more frequent monitoring then a single or dual chamber pacemaker. Therefore, Florida Medicare will allow routine electronic analysis of a pacing cardioverter-defibrillator (single and dual chamber) at one month following implantation and then every three months thereafter. Transtelephonic monitoring of a pacemaker cardioverter-defibrillator is noncovered and should be billed with procedure code A9270 (non-covered item or service).

HCPCS Section & Benefit Category

Medicine/Cardiovascular

**CPT Codes**

<table>
<thead>
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Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
- 426.0-426.9
- 427.0-427.9
- 4294
- 780.2
- 785.1
- 785.1
- 996.01
- 996.04
- 996.09
- 996.09
- 996.09
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- 996.09

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Transtelephonic monitoring of a pacemaker cardioverter-defibrillator is noncovered.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
Procedure codes 93741-93744 are intended to be reported for postimplantation electronic analysis performed in an office or outpatient setting, and do not involve induction of an arrhythmia. It is not appropriate to bill for procedure codes 93741-93744 at the time of pacemaker cardioverter-defibrillator (procedure codes 33216, 33217, 33240, 33245, 33246, and 33249) insertion.

The pacemaker analysis codes 93731-93736 are intended to be reported for subsequent encounters separate from the insertion procedure. Therefore, it would be inappropriate to bill for the pacemaker analysis codes 93731, 93732, 93734, 93735 or 93736 at the time of single-chamber or dual-chamber pacemaker (procedure codes 33212-33213) insertion.

If the electronic analysis of the pacemaker, automatic implantable cardiac defibrillator or pacing cardioverter-defibrillator is being performed for routine follow-up of that device, then the appropriate "V" diagnosis should be billed.

Transtelephonic monitoring of pacemaker cardioverter-defibrillators are noncovered and should be billed with procedure code A9270 (noncovered item or service).

Documentation Requirements
Medical record documentation maintained by the performing provider must clearly indicate the medical necessity of the service being billed and must demonstrate the medical necessity of the services performed in excess of the established frequency guidelines. In addition, the documentation must support that the service was performed. This information is normally found in the office/progress notes, hospital records, testing results.

Also, a physician’s prescription for monitoring is required and must be renewed annually when the monitoring is performed by a commercial monitoring service or an outpatient hospital department. In addition, the documentation must indicate the date and type of device implanted.

For services performed by entities other than the attending physician, such as monitoring services and pacemaker clinics, it is expected that the medical record documentation will demonstrate how the information obtained is used in the management of the patient.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage” and/or Medical Necessity” section of this policy.

Utilization Guidelines
The frequency of transtelephonic monitoring of cardiac pacemakers and the frequency of monitoring of lithium-battery pacemakers in a pacemaker clinic are identified in the Coverage Issues Manual, Section 50-1. These guidelines are identified in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Other Comments
N/A

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Florida Chapter of the American College of Cardiology.

The Carrier Advisory Committee Meeting was held on November 11, 2000.

Start Date of Comment Period
11/03/2000

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: Original PCR B2001- 063
Start Date of Comment Period: 11/03/2000
Start Date of Notice Period: 02/01/2001

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
93965: Non-Invasive Evaluation of Extremity Veins

The complete local medical review policy (LMRP) for Non-Invasive Evaluation of Extremity Veins was published in the July/August 2000 Medicare B Update! (pages 59-61). Since that time, an additional ICD-9-CM code [782.3 (edema)] has been added to the policy, effective for services processed on or after January 1, 2001.

All other requirements listed in the policy continue to apply. For specific information, please refer to the “ICD-9-CM Codes that Support Medical Necessity,” “Coding Guidelines,” “Documentation Requirements,” and “Advance Notice Statement” sections of the policy as published in the July/August 2000 Update!

Medical Policy Procedures: 95115

Policy Number
95115

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Allergen Immunotherapy

AMA CPT Copyright Statement
CPT codes, descriptions, and other data only are copyright 1998 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Apply.

HCFA National Coverage Policy
Medicare Carriers Manual, Section 15050

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
10/16/2000

Revision Effective Date
01/01/2001

Revision Ending Effective Date
12/31/2000

Policy Ending Date
N/A

LMRP Description
Allergen immunotherapy (desensitization), also referred to as specific immunotherapy, is the subcutaneous introduction of increasing doses of allergens to which the patient is sensitive. Allergen immunotherapy is antigen-specific; thus the sensitivity of the patient must be known before formulating extracts for therapy. The antigenic cross-reactivity of extracts should be known by the physician to optimize use of the minimum number of separate extracts given per single injection. In this way, the maximum amount of protein antigen can be given. This therapy is generally reserved for patients with significant relapsing, subacute to chronic symptoms, where the symptoms are likely caused by allergic pathology, and in situations where other means of conservative therapy (including avoidance) have failed to control the symptoms adequately, or avoidance of the relevant allergen (e.g., dust mites, pollen, mold) is impractical.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will provide coverage for allergen immunotherapy for patients with allergic rhinitis, allergic conjunctivitis, or asthma when all four of the following criteria are met:

(1) the patient must have significant exposure to an allergen;
(2) the patient must have demonstrated a significant level of sensitivity to the allergen;
(3) the pattern of symptoms must conform to the pattern of exposure; and
(4) other means of conservative therapy (including avoidance) have failed to control the symptoms, or avoidance of the relevant antigen (e.g., dust mites, pollen, mold) is impractical.

Generally, the course of allergen immunotherapy, if successful, should be continued until the patient has been symptom-free or has had substantially reduced symptoms for 1 to 2 years and in most cases from 3 to 5 years. If no response has occurred after 1 year at maintenance dose, the patient’s sensitivities should be reviewed. All patients on immunotherapy should be encouraged to maintain environmental control and may have to use concomitant medication, such as antihistamines.

HCPCS Section & Benefit Category
Medicine/Allergy and Clinical Immunology

HCPCS Codes
95115 95117 95165

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>372.05</td>
<td>477.8</td>
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<td>372.14</td>
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<tr>
<td>477.0</td>
<td>493.90-493.92</td>
</tr>
</tbody>
</table>

NOTE: ICD-9-CM code 989.5 is applicable to codes 95115 and 95117 only; code 95165 represents a non-venom antigen

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A
Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denial
Allergen immunotherapy performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)
Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses
N/A

Coding Guidelines
Evaluation and Management services (99201-99215) are allowed in addition to 95115 or 95117 only when separately identifiable services are provided at the same time.

HCPCS codes 95115 and 95117 reflect the administration (injection) of the allergic extract, when the extract is not included in the code descriptor. They do not include the provision or preparation of the extract. For example: An allergist provides a patient with an allergic extract. The patient brings the extract to a family or primary care practitioner who administers the injection(s).

HCPCS code 95165 does not include the injection procedure(s). Therefore, when a physician prepares the allergenic extract(s) (same or different antigens), and administers the extract(s) using single or multiple injections, code 95165 should be reported in addition to either 95115 or 95117.

Code 95165 represents multiple dose vials of non-venom antigens. Some non-venom antigens cannot be mixed together (i.e., they must be prepared in separate vials). Therefore, some patients will be injected at one time from one vial (containing in one mixture all of the appropriate antigens), while other patients will be injected at one time from more than one vial. A dose of code 95165 is defined as one cc aliquot from a single multidose vial.

HCPCS codes 95120–95134 represent complete services (i.e., services that include the injection services as well as the antigen and its preparation). These codes are not valid for Medicare purposes; therefore, no reimbursement will be provided.

Documentation Requirements
Medical record documentation maintained by the treating physician must clearly document the medical necessity to initiate allergen immunotherapy and the continued need thereof. The documentation should include:

- A history and physical that documents the following: a complete allergic history and physical examination; correlation of symptoms; occurrence of symptoms; exposure profile; documentation of allergic sensitization by accepted means and where attempts at avoidance have proven unsuccessful (or the impracticality of avoidance exists); and a copy of the sensitivity results.
- Progress notes that document physician management during the course of the allergic disease, anticipated length of treatment, and explanation of any deviations from normal treatment frequency.

Utilization Guidelines
N/A

Other Comments
Terms Defined:
Allergen: any substance that indicates a state of, or brings on manifestations of, allergy.
Allergy: an altered reaction of body tissues to a specific substance (allergen) which in nonsensitive persons will, in similar amounts, produce no effect.
Asthma: a reversible obstructive lung disorder characterized by increased responsiveness of the airways.
Immunotherapy: the production or enhancement of immunity.
Rhinitis: inflammation of the nasal mucosa.

Sources of Information
Sources of information may be found online under LMRPs in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from numerous societies.

Carrier Advisory Committee held on May 13, 2000.

Start Date of Comment Period
N/A

Start Date of Notice Period
02/01/2001

Revision History
Revision Number: 1
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS update

Advance Notice Statement
Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Electroencephalography (EEG) (Ambulatory/24 hour) Long-term (24-hour) Ambulatory EEG Monitoring (95950, 95951, 95953, 95956):

Ambulatory or 24-hour electroencephalographic (EEG) monitoring (95950-95951, 95953, 95956) is covered for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG. Ambulatory EEG can be utilized in the differential diagnosis of syncope and transient ischemic attacks if not elucidated by conventional studies. Ambulatory EEG should always be preceded by a resting EEG (95816, 95819, 95822, 95827).

Electroencephalography (Resting):

HCPCS Section & Benefit Category
Medicine/Neurology and Neuromuscular Procedures

CPT Codes
95816  95819  95950  95951  95953  95956
95819  95827  95951  95956

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
(For Procedure code 95819)
291.0  331.2  386.2
293.0  332.0  430
294.0  333.6  431
294.8  342.00-342.02  433.20-433.21
294.9  342.10-342.12  435.0-435.9
296.00-296.06  342.80-342.82  435.8-435.9
296.10-296.16  342.90-342.92  437.1-437.2
296.20-296.26  345.00-345.01  780.1
296.30-296.36  345.10-345.11  780.2
296.40-296.46  345.2-345.3  780.31-780.39
296.50-296.56  345.40-345.41  780.4
296.60-296.66  345.60-345.61  780.9
296.7  345.70-345.71  781.0
296.80-296.82  345.80-345.81  781.2
296.89  345.90-345.91  784.3
296.90  346.00-346.01  852.00-852.09
296.99  346.10-346.11  852.10-852.19
300.10-300.11  346.20-346.21  852.20-852.29
306.9  346.80-346.81  852.30-852.39
306.9  346.90-346.91  852.40-852.49
310.1  348.1  852.50-852.59
310.2  348.3  853.00-853.09
322.9  349.0  853.10-853.19
323.0  349.82  854.00-854.09
324.0  379.40  854.10-854.19
331.0  379.50
331.1

(For Procedure Codes 95950, 95951, 95953, 95956)
006.5  036.0-036.1  063.0-063.9
013.00-013.06  045.00-045.03  064
013.10-013.16  045.10-045.13  071
013.20-013.26  045.20-045.23  072.1
013.30-013.36  045.90-045.93  072.2
013.40-013.46  053.0  191.0-191.9
013.50-013.56  053.10-053.19  192.0
013.60-013.66  054.72  192.1
013.80-013.86  056.00-056.09  225.0
013.90-013.96  062.0-062.9  225.2
LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

Diagnoses that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denial

Telephonically transmitted EEG’s are not covered for determining electrical inactivity (e.g., brain death).

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnoses

N/A

Coding Guidelines

Use of technical component (TC) or professional component (26) modifier is appropriate in billing diagnostic procedures.

Documentation Requirements

Appropriate diagnosis criteria is required.

The provider has a responsibility to ensure the medical necessity for these procedures and must maintain documentation for postpayment audit.

Utilization Guidelines

N/A

Other Comments

Terms Defined:

Consciousness: a state of awareness.

Diathesis: predisposition to certain disease conditions.

Electroencephalogram: recording of electrical activity of the brain.

Sources of Information

N/A

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with the contractor’s Advisory Committee, which includes representatives from the Neurology Workgroup.

Start Date of Comment Period

N/A

Start Date of Notice Period

02/01/2001

Revision History

Revision Number: 10 PCR B2001- 060
Start Date of Comment Period: N/A
Start Date of Notice Period: 02/01/2001

2nd Qtr 2001 Update!

Revised Effective Date: 02/05/2001
Explanation of Revision: A revision was made to add ICD-9-CM code 294.8 to the policy.

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 4 for details concerning ABNs.
Justice Recovers Record $1.5 Billion in Fraud Payments
Highest Ever for One Year Period

The following is reprinted from a November 2, 2000, Department of Justice press release.
The United States [Justice Department] collected a record $1.5 billion in civil fraud recoveries during the past fiscal year - an increase of almost 50 percent above the largest previous annual recovery in 1997, Attorney General Janet Reno announced today.

“This new record demonstrates the Department’s continued commitment to ensure the proper use of taxpayer monies,” said Attorney General Reno. “The Department will continue to pursue those who seek to defraud the United States, whether by providing defective products, billing for services that were not provided or otherwise misusing public funds for private gain.”

Approximately $1.2 billion of the Department’s settlements and judgments occurred in connection with cases filed under the federal whistleblower statute, which allows individuals who disclose fraud to share in the government’s recovery. To date, payments to whistleblowers for the past fiscal year (October 1, 1999 - September 30, 2000) have totaled approximately $173 million.

Health care fraud cases once again topped the list of annual recoveries, totaling more than $840 million. This amount included the largest civil fraud recovery ever - a $385 million settlement with Fresenius Medical Care to resolve sweeping allegations of wrongdoing by its kidney dialysis subsidiary. The Department also recovered $170 million from Beverly Enterprises, Inc., the largest nursing home operator in the United States, for alleged false billings to Medicare involving over 400 nursing homes around the country.

“Health care fraud imposes enormous costs on American taxpayers and decreases the quality of care provided to patients,” said Assistant Attorney General David W. Ogden of the Department’s Civil Division. “Although the vast majority of health care providers are honest and provide the highest standard of care, stopping those who prey on the health care system remains one of the Department’s top law enforcement priorities.”

After health care, the largest category of fraud recoveries involved the production of oil and other minerals from public lands. The Department recovered more than $230 million from companies alleged to have underpaid royalties on such production, including $95 million from Chevron, $56 million from Shell, $32 million from BP Amoco, $26 million from Conoco and $11.9 million from Devon Energy.

The Department’s recoveries also included over $140 million in settlements with twenty-five brokerage firms. These companies allegedly sold open market securities with artificially low yields to municipalities refunding tax-exempt bonds, thereby reducing the municipalities’ purchase of special low-interest Treasury bonds. Defense procurement fraud accounted for another $100 million in recoveries, including up to $54 million from the Boeing Corporation to resolve allegations that it placed defective transmission gears in army Chinook helicopters.

The Department’s record level of recoveries for fiscal year 2000 also included the following:

- $74 million from Anthem Blue Cross and Blue Shield, formerly the Medicare Part A intermediary for Connecticut, to resolve claims that it underreported the total amount of interim payments by hospitals to improve scores on Health Care Financing Administration evaluations;
- $53 million from Gambro Healthcare Patient Services, Inc. to resolve allegations that it billed Medicare for unnecessary laboratory tests;
- $35 million from Jacobs Engineering Group in connection with allegations that it improperly charged overhead costs to various government contracts;
- $33.5 million from Toshiba Corporation to settle claims arising from its sale of defective computer laptops to various federal agencies;
- $31 million from Community Health Systems for allegedly “upcoding” - the improper assignment of diagnostic codes to hospital inpatient discharges for the purpose of increasing reimbursement amounts to various hospital services; and
- $16.6 million from two government contractors, CRSS, Inc. and Metcalf & Eddy, for alleged false billings in connection with the construction of an air defense system in Saudi Arabia.
Home Health Prospective Payment System/Consolidated Billing

The Balanced Budget Act of 1997 required consolidated billing of all home health services while a beneficiary is under a home health plan of care authorized by a physician. Consequently, billing for all such items and services will be made to a single home health agency (HHA) overseeing that plan. Information concerning the physician’s role in this was originally published in the May/June 2000 Medicare B Update! (pages 58-59).

Program Memoranda (PMs) AB-00-65, dated June 2000, B-00-50, dated October 2000, and AB-00-112 dated November 2000 provide instructions for the implementation of consolidated billing for the Home Health Prospective Payment System (HHPPS) for both intermediaries and carriers. The law states that payment will be made to the primary HHA whether or not the item or service was furnished by the agency, by others under arrangement to the primary agency, or when any other contracting or consulting arrangements existed with the primary agency, or “otherwise.” Payment for all items is scheduled in the home health PPS episode payment that the primary HHA receives.

Types of services that are subject to the home health consolidated billing provision include:

- Skilled nursing care;
- Home health aide services;
- Physical therapy;
- Speech-language pathology;
- Occupational therapy;
- Medical social services;
- Routine and non-routine medical supplies;
- Medical services provided by an intern or resident-in-training of a hospital, under an approved teaching program of the hospital, in the case of a HHA that is affiliated or under common control with that hospital;

- Care for homebound patients involving equipment too cumbersome to take to the home.

Effective for claims processed on or after October 30, 2000, for dates of service on or after October 1, 2000, services that should not be billed separately when a patient is under an established 60-day home health POC episode will be denied. For Part B, those services include Physical Therapy, Speech-Language Pathology and Occupational Therapy.

CPT codes affected are:

90901, 90911, 92506, 92507, 92508, 92510, 92525, 92526, 92597, 92598, 96105, 97001, 97002, 97003, 97004, 97012, 97014, 97016, 97018, 97020, 97022, 97024, 97026, 97028, 97032, 97033, 97034, 97035, 97036, 97039, 97110, 97112, 97113, 97116, 97122, 97124, 97139, 97140, 97150, 97250, 97260, 97261, 97265, 97504, 97520, 97530, 97535, 97537, 97542, 97545, 97546, 97703, 97750, 97770, 97799.

Services provided by certain non-medical suppliers that are processed by the Durable Medical Equipment Regional Carrier (DMERC) are also affected. Providers may contact the Region C DMERC, Palmetto GBA, for more information. Palmetto may be contacted at (866) 238-9650, at the following address, or online at http://www.palmettogloba.com.

Palmetto GBA Medicare
DMERC Operations
P.O. Box 100141
Columbia, SC 29202-3141
The following article was provided by the Health Care Financing Administration’s (HCFA) south Florida field office.

The Florida Board of Medicine has adopted a “physician-in-charge” rule designed to combat health care fraud associated with Florida clinics. The new rule found at 64B8-9.0075, Standards of Practice in Certain Office Settings, became effective November 13, 2000, and impacts Florida licensed physicians and physician assistants (PAs) employed in nonphysician-owned clinics across the State. Physicians and PAs working in hospitals, federally qualified health clinics, and certain other practice settings with risk management and oversight programs are not subject to these new requirements.

Existing standards of practice and care require Florida licensed physicians and PAs to provide their patients with appropriate medical care under sanitary conditions, pursuant to informed consent, and to adequately document and lawfully bill for that care. To ensure greater compliance with those standards by all Florida licensed physicians and PAs, the new Board rule lays out the conditions under which responsibility for ensuring compliance may be met.

Physicians and PAs working in settings not under the ownership and control of an actively licensed Florida physician “may reasonably rely upon” a “physician-in-charge” to ensure compliance only if the physician-in-charge has filed a notarized statement on a form approved by the Board of Medicine. This physician-in-charge accepts the following responsibilities on behalf of one or more named licensed physicians or physician assistants in the practice setting to ensure that:

- all staff in the practice setting are licensed or certified as required by law and that licensure or certification documentation is maintained at the practice setting and immediately available upon request to Department of Health or Agency for Health Care Administration investigators;
- any medical services provided by staff at the practice setting are appropriately supervised as required by law;
- the practice setting complies with the relevant sections of Chapters 455, 458, 465, 499 and 893, Florida Statutes, and the relevant Board rules, to include but not limited to, rules regarding office surgery, medical records keeping, and the reporting of adverse incidents; and
- all billings are not fraudulent and that includes a systematic review of the medical services provided, the dates of service, procedure and diagnostic codes, and the name of the provider.

An original, notarized physician-in-charge statement must be filed with the Board of Medicine. Copies of the statement are to be maintained at the practice site and be immediately available, upon request, to State and Federal regulators.

Failure by physicians and physician assistants to comply with the physician-in-charge rule may result in referral to the Board of Medicine for disciplinary action. Furnishing false information on the physician-in-charge registration form is cause for denial, suspension or revocation of a license to practice medicine in the State of Florida. Providing false information may also result in criminal penalties pursuant to Florida Statutes.

First Coast Service Options, Inc. (FCSO), the Medicare Part B carrier for Florida, is incorporating the physician-in-charge requirement into its provider enrollment procedures and site visits. Applications for provider numbers from nonphysician-owned clinics that fail to document physician or nonphysician compliance with the requirements of this rule or the standards of practice and care may be denied. In addition, staff from HCFA, FCSO, and various regulatory bodies may seek proof of a clinic’s compliance with the physician-in-charge requirement through site visits and other means and require corrective action for noncompliance.

The Florida Board of Medicine is using a variety of methods to inform the medical community, including their newsletter and email distribution list, as well as via the Florida Medical Association and the Florida Academy of Physician Assistants. Your prompt review of your compliance with these requirements will be greatly appreciated.
Crossover Updates

The following updates have been performed to the Florida Medicare Part B Crossover Insurers list. These changes can be viewed in the Part B Medigap section on our provider Website - www.floridamedicare.com. An updated “Understanding Crossover” document and Medigap Listing is available on the Website as well.

Automatic Crossover

• New Crossover Insurer

The following private insurers have been added to our list of Automatic Crossover Insurers:

- Great West Life & Annuity Insurance Company
- Stirling & Stirling, Inc.
- United Teachers Associates Insurance Company (UTA)

• Updates to Crossover Insurers

Humana

Humana Inc. has signed an agreement with United Teachers Associates Insurance Company (UTA) to transfer the administration of the Medicare Supplement business to UTA. This transition is effective November 1, 2000. **Humana will no longer be receiving Medicare Automatic crossover claims.**

Medigap Crossover

• Address Change

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<th>Name/Address</th>
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| 57003  | Medical Service Corporation of Eastern Washington
|       | PO Box 3050                           |
|        | Spokane WA 99220                      |

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<tr>
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• Name Change

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<tr>
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<td>PAAC Health Plan</td>
<td>Health Net Plan of Oregon</td>
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• Exempt Non-Medigap Insurers

The following insurers do not offer and/or process Medicare Supplemental plans and are exempt from the Medigap crossover process. The Medigap insurer list has been updated to change each insurer identification number listed below to an exempt status. Each number listed is inactive and payment information will not be crossed over to these insurers.

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HCFA Announces Revised Fee Policy in Fiscal Year 2001 For Provider Education and Training Activities

As a Medicare contractor, First Coast Service Options, Inc. (FCSO) develops and delivers education and training seminars, publications, and resources prescribed and authorized by the Health Care Financing Administration (HCFA). Many activities identified and funded by HCFA as required curricula are provided free of charge to the provider and supplier communities.

In recent years, HCFA has supported significant expansions in provider education and training efforts that extend beyond the core curricula Medicare contractors have traditionally presented. This expansion has been in response to major program changes, and the need to educate providers and suppliers on specific Medicare regulations and procedures. This has allowed FCSO to present additional seminars, publications, and resources by assessing fees. The fees defray program expenses, and are never for profit. The topics are of significant interest, and have been well received by providers and suppliers.

Effective June 2000, HCFA advised Medicare contractors to discontinue charging fees for education and training activities, and initiated a review of its policies for such activities. FCSO conveyed this change in communications to key provider and supplier organizations, and through its customer service professionals. In announcing performance expectations for Fiscal Year 2001, HCFA has provided further guidelines. Medicare contractors are authorized to resume charging to recover expenses associated with performing provider training and education initiatives. Fair and reasonable costs are authorized for discretionary activities deemed supplemental or enhancements to core educational requirements. A variety of events and activities within the required curriculum will continue to be presented at no cost to providers and suppliers.

Presently, FCSO’s education departments are developing enhanced and supplemental programs and resources to support improved Medicare education. These initiatives, many of which are customer requested, will be announced soon. FCSO will use the revenue generated to cover the cost of the education and training provided. Event information and registration forms will be posted on our provider Website - www.floridamedicare.com - under the “Education” page. Providers are invited to check this site regularly to access the latest event and resource information.

MEDICARE MADE EASY
FOR PART B PROVIDERS

Presented by First Coast Service Options, Inc.
Your Florida Medicare Contractor

Five Free Medicare Part B Sessions for Physicians, Suppliers, Office Managers, Non-Physician Practitioners, and Billing Staff

- Are you a new Medicare Provider?
- Do you have new office staff?
- Do you need to improve your office’s efficiency?
- If you answered “yes” to any of these questions, this seminar was designed to meet your needs.

<table>
<thead>
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<th>DATE</th>
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<tbody>
<tr>
<td>February 16, 2001</td>
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</tr>
<tr>
<td>May 31, 2001</td>
<td>Pensacola</td>
</tr>
<tr>
<td>June 19, 2001</td>
<td>Orlando</td>
</tr>
<tr>
<td>July 24, 2001</td>
<td>Tampa</td>
</tr>
</tbody>
</table>

Register today! Seating is limited!

Please see next page for schedule and visit our Web site, www.floridamedicare.com, for specific seminar locations.
## TRACK 1

<table>
<thead>
<tr>
<th>Session Times</th>
<th>Course</th>
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<tbody>
<tr>
<td>8:00 - 9:00 a.m.</td>
<td>General Session</td>
</tr>
<tr>
<td>9:00 - 9:15 a.m.</td>
<td>Break</td>
</tr>
<tr>
<td>9:15 - 10:45 a.m.</td>
<td>HCFA-1500 Claim Filing</td>
</tr>
<tr>
<td>10:50 a.m. - 12:20 p.m.</td>
<td>Inquiries, Appeals, and Overpayments</td>
</tr>
<tr>
<td>12:20 p.m. - 1:20 p.m.</td>
<td>LUNCH</td>
</tr>
<tr>
<td>1:30 - 3:00 p.m.</td>
<td>Reimbursement Efficiency for Part B</td>
</tr>
<tr>
<td>3:15 - 3:45 p.m.</td>
<td>Panel Discussion</td>
</tr>
</tbody>
</table>

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<tr>
<td>9:15 - 10:45 a.m.</td>
<td>E/M Coding</td>
</tr>
<tr>
<td>10:50 a.m. - 12:20 p.m.</td>
<td>Medical Review</td>
</tr>
<tr>
<td>12:20 p.m. - 1:20 p.m.</td>
<td>LUNCH</td>
</tr>
<tr>
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<td>Fraud and Abuse</td>
</tr>
<tr>
<td>3:15 - 3:45 p.m.</td>
<td>Panel Discussion</td>
</tr>
</tbody>
</table>
ORDER FORM – 2001 PART B MATERIALS

The following materials are available for purchase. To order these items, please complete and submit this form along with your check/money order payable to First Coast Service Options, Inc. with the account number listed by each item.

PLEASE NOTE: Payment for fee schedules cannot be combined with payment for other items; separate payments are required for purchases of items from different accounts.

<table>
<thead>
<tr>
<th>NUMBER ORDERED</th>
<th>ITEM</th>
<th>ACCOUNT NUMBER</th>
<th>COST PER ITEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Medicare B Update! Subscription</strong> – One copy of the Update! is sent free of charge to individual providers and Professional Association (PA) groups who bill at least one claim to Medicare Part B of Florida for processing during the twelvemonths prior to the release of each issue. Non-provider entities or providers who need additional copies at other office locations may purchase an annual subscription. This subscription includes all issues published during calendar year 2001 (back issues sent upon receipt of order).</td>
<td>756245</td>
<td>$75.00</td>
</tr>
<tr>
<td></td>
<td><strong>2001 Fee Schedule</strong> – One copy of the Medicare Part B Physician and Non-Physician Practitioner Fee Schedule is sent free of charge in mid-November to individual providers and Professional Association (PA) groups who bill at least one claim to Medicare Part B of Florida for processing during the preceding six months. The Fee Schedule contains calendar year 2001 payment rates for all Florida localities. These fees apply to services performed between January 1 and December 31, 2001. These items include the payment rates for injectable drugs, but do not include payment rates for clinical lab services, mammography screening, or DMEPOS items. Note also that revisions to fees may occur; these revisions will be published in future editions of the Medicare B Update! Non-provider entities or providers who need additional copies at other office locations may purchase additional copies.</td>
<td>756250</td>
<td>$20.00</td>
</tr>
<tr>
<td></td>
<td><strong>Procedure-to-Diagnosis Relationship Report</strong> – This is a listing of the most current file used during claims processing to determine coverage for procedures subject to specific diagnosis criteria. This document is designed to assist providers by outlining diagnosis criteria in order to limit their financial liability for these procedures. Available in four single issues or an annual subscription that includes one update quarterly.</td>
<td>756245</td>
<td>Annual (4 issues) $60.00 Single Issue $20.00</td>
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</tbody>
</table>

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Note: The Medicare B Update! and 2001 Medicare Part B Physician and Non-Physician Practitioner Fee Schedule are available free of charge online at www.FloridaMedicare.com.
IMPORTANT ADDRESSES

CLAIMS SUBMISSIONS

Routine Paper Claims
Medicare Part B
P. O. Box 2525
Jacksonville, FL 32231-0019

Participating Providers
Medicare Part B Participating Providers
P. O. Box 44117
Jacksonville, FL 32231-4117

Chiropractic Claims
Medicare Part B Chiropractic Unit
P. O. Box 44067
Jacksonville, FL 32231-4067

Ambulance Claims
Medicare Part B Ambulance Dept.
P. O. Box 44099
Jacksonville, FL 32231-4099

Medicare Secondary Payer
Medicare Part B Secondary Payer Dept.
P. O. Box 44078
Jacksonville, FL 32231-4078

ESRD Claims
Medicare Part B ESRD Claims
P. O. Box 45236
Jacksonville, FL 32232-5236

COMMUNICATIONS

Review Requests
Medicare Part B Claims Review
P. O. Box 2360
Jacksonville, FL 32231-0018

Fair Hearing Requests
Medicare Part B Fair Hearings
P. O. Box 45156
Jacksonville, FL 32232-5156

Administrative Law Judge Hearing
Administrative Law Judge Hearing
P. O. Box 45001
Jacksonville, FL 32231-5001

Status/General Inquiries
Medicare Part B Correspondence
P. O. Box 2360
Jacksonville, FL 32231-0018

Overpayments
Medicare Part B Financial Services
P. O. Box 44141
Jacksonville, FL 32231-0048

DURABLE MEDICAL EQUIPMENT (DME)

DME, Orthotic or Prosthetic Claims
Palmetto GBA Medicare
DMERC Operations
P. O. Box 100141
Columbia, SC 29202-3141

ELECTRONIC MEDIA CLAIMS (EMC)

EMC Claims, Agreements and Inquiries
Medicare EDI
P. O. Box 44071
Jacksonville, FL 32231-4071

MISCELLANEOUS

Provider Participation and Group Membership Issues; Written Requests for UPINS, Profiles & Fee Schedules:
Medicare Registration
P. O. Box 44021
Jacksonville, FL 32231-4021

Provision Change of Address:
Medicare Registration
P. O. Box 44021
Jacksonville, FL 32231-4021

Provider Registration Department
Blue Cross Blue Shield of Florida
P. O. Box 41109
Jacksonville, FL 32231-1109

Provider Education:
For Educational Purposes and Review of Customary/Prevailing Charges or Fee Schedule:
Medicare Part B
Medicare Education and Outreach
P. O. Box 45157
Jacksonville, FL 32231

Limiting Charge Issues:
For Processing Errors:
Medicare Part B
P. O. Box 2360
Jacksonville, FL 32231-0048

For Refund Verification:
Medicare Part B
Compliance Monitoring
P. O. Box 2078
Jacksonville, FL 32231-0048

Medicare Claims for Railroad Retirees:
MetraHealth RRB Medicare
P. O. Box 10066
Augusta, GA 30999-0001

Fraud and Abuse
Medicare Fraud Branch
P. O. Box 45087
Jacksonville, FL 32231

PHONE NUMBERS

BENEFICIARY
Outside Duval County (in Florida):
(800) 333-7586

Duval County (or outside Florida):
(904) 355-3680

Hearing Impaired:
(800) 754-7820

Note: The toll-free customer service lines are reserved for Medicare beneficiaries only. Use of this line by providers is not permitted and may be considered program abuse.

PROVIDER
Toll-Free (Replaces ARU and Specialty Lines)
(877) 847-4992

EMC
Format Issues & Testing:
(904) 354-5977

Start-Up & Front-End Edits/Rejects:
(904) 791-8767

Electronic Remittance Advice, Electronic Claim Status, & Electronic Eligibility:
(904) 791-6895

PC-ACE Support:
(904) 355-0313

Help Desk
(Confirmation/Transmission):
(904) 791-9880

OCR
Printer Specifications/Test Claims:
(904) 791-8132

DME, Orthotic or Prosthetic Claims
Palmetto GBA Medicare
(803) 735-1034

WEBSITES

PROVIDER
Florida
www.floridamedicare.com

Health Care Financing Administration
www.hcfa.gov

BENEFICIARY
Florida
www.medicarefla.com

Health Care Financing Administration
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